AMGEN INC
Form 10-K
February 13, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K
(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number 001-37702
Amgen Inc.
(Exact name of registrant as specified in its charter)

| | |
|---|---|
| Delaware | 95-3540776 |
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| One Amgen Center Drive, Thousand Oaks, California | 91320-1799 |
| (Address of principal executive offices) | (Zip Code) |

(805) 447-1000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Name of each exchange on which registered |
|---|---|
| Common stock, $0.0001 par value | The NASDAQ Global Select Market |

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No ý
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ý No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| Large accelerated filer | Accelerated filer | Non-accelerated filer | Smaller reporting company | Emerging growth company |
|---|---|---|---|---|
| ý | ¨ | ¨ | ¨ | ¨ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ¨ No ý

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $119,629,312,769 as of June 30, 2018.(A)

(A) Excludes 884,143 shares of common stock held by directors and executive officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding, at June 30, 2018. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

622,278,034
(Number of shares of common stock outstanding as of February 7, 2019)

DOCUMENTS INCORPORATED BY REFERENCE
Specified portions of the registrant's Proxy Statement with respect to the 2019 Annual Meeting of Stockholders to be held May 21, 2019, are incorporated by reference into Part III of this annual report.

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PART I

Item 1. BUSINESS

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is committed to unlockin the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen was incorporated in California in 1980 and became a Delaware corporation in 1987. We have a presence in approximately 100 countries worldwide. Amgen operates in one business segment: human therapeutics.

Significant Developments

Following is a summary of significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2017, and in early 2018.

Products/Pipeline

Oncology/Hematology

BLINCYTO® (blinatumomab)

- In March 2018, we announced that the U.S. Food and Drug Administration (FDA) approved under accelerated approval the supplemental Biologics License Application (sBLA) for BLINCYTO® for the treatment of adults and children with B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease greater than or equal to 0.1 percent.
- In June 2018, we announced that the European Commission (EC) granted a full marketing authorization for BLINCYTO® based on the overall survival data from the phase 3 TOWER study in adult patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL.
- In August 2018, we announced that the EC approved an expanded indication for BLINCYTO® as monotherapy for the treatment of pediatric patients aged one year or older with Philadelphia chromosome-negative CD19 positive B-cell precursor ALL, which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.
- In January 2019, we announced that the EC approved an expanded indication for BLINCYTO® as monotherapy to include adult patients with Philadelphia chromosome-negative CD19 positive B-cell precursor ALL in first or second complete remission with minimal residual disease greater than or equal to 0.1 percent.

KYPROLIS® (carfilzomib)

- In January 2018, we announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion resulting in a label variation for KYPROLIS® to include updated overall survival data from the phase 3 head-to-head ENDEAVOR (RandomizEd, OpeN Label, Phase 3 Study of Carfilzomib Plus DExamethAsone Vs Bortezomib Plus DexamethasOne in Patients With Relapsed Multiple Myeloma) study in patients with relapsed or refractory multiple myeloma.
- In April 2018, we announced that the CHMP of the EMA adopted a positive opinion resulting in a label variation for KYPROLIS® to include the final overall survival data from the phase 3 ASPIRE (CArfilzomib, Lenalidomide, and DexamethaSone versus Lenalidomide and Dexamethasone for the treatment of PatIents with Relapsed Multiple MyEloma) study. In June 2018, we announced that the FDA approved the supplemental New Drug Application (sNDA) to add the positive overall survival data from the ASPIRE study to the U.S. Prescribing Information for patients with relapsed or refractory myeloma.

- In October 2018, we announced that the FDA approved the sNDA to expand the Prescribing Information for KYPROLIS® to include a once-weekly dosing option in combination with dexamethasone for patients with relapsed or refractory multiple myeloma.

Neulasta® (pegfilgrastim)

- In February 2018, we announced that the CHMP of the EMA issued a positive opinion recommending a label variation for Neulasta® to include the Neulasta® Onpro® kit.

Cardiovascular

Repatha® (evolocumab)

- In May 2018, we announced that the EC approved a new indication in the Repatha® label for adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease) to reduce cardiovascular risk by lowering low-density lipoprotein (LDL) cholesterol levels.
- In October 2018, we announced a set of new National Drug Codes (NDCs) to make Repatha® available at a 60% lower list price of $5,850 per year to address affordability for patients, particularly those on Medicare.
- In January 2019, we announced that the National Medical Products Administration approved a new indication for Repatha® as the first PCSK9 inhibitor in China for adults with established atherosclerotic cardiovascular disease to reduce the risk of myocardial infarction, stroke and coronary revascularization.

Neuroscience

Aimovig® (erenumab-aooe)

- In May 2018, we announced that the FDA approved Aimovig® for the preventive treatment of migraine in adults. Aimovig® is part of a joint development and commercialization collaboration with Novartis AG (Novartis).

Inflammation

Tezepelumab

- In September 2018, we announced that the FDA granted Breakthrough Therapy Designation for tezepelumab in patients with severe asthma without an eosinophilic phenotype. Tezepelumab is being developed jointly in collaboration with AstraZeneca plc (AstraZeneca).

Bone health

EVENITY™* (romosozumab)

- In January 2019, we and UCB, our global collaboration partner in the development of EVENITY™, announced that the FDA Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) voted to recommend approval of EVENITY™ for the treatment of osteoporosis in postmenopausal women at high risk for fracture. Also in January 2019, the Japanese Ministry of Health, Labor and Welfare granted a marketing authorization for the treatment of osteoporosis in men and postmenopausal women at high risk of fracture.

Prolia® (denosumab)

- In May 2018 and June 2018, the FDA and the EC, respectively, approved a new indication for Prolia® for the treatment of glucocorticoid-induced osteoporosis in adult patients at high risk of fracture.

XGEVA® (denosumab)

- In April 2018, we announced that the EC approved an expanded indication for XGEVA® for the prevention of skeletal-related events (SREs) in patients with multiple myeloma.

Biosimilars

AMGEVITA™ (biosimilar adalimumab)

- In October 2018, we began launching AMGEVITA™ in markets across Europe.

KANJINTI™* (biosimilar trastuzumab / formerly ABP 980)

- In May 2018, the EC granted marketing authorization for KANJINTI™, a biosimilar candidate to Herceptin®, for the treatment of HER2-positive metastatic breast cancer, HER2-positive early breast cancer and HER2-positive metastatic adenocarcinoma of the stomach or gastroesophageal junction. KANJINTI™ is being developed in collaboration with Allergan plc (Allergan).
- In May 2018, we announced that we received a Complete Response Letter from the FDA for the Biologics License Application (BLA) for KANJINTI™. In December 2018, we refiled our BLA with the FDA for KANJINTI™.

ABP 710 (biosimilar infliximab)

- In June 2018, we announced results from a phase 3 study evaluating the efficacy and safety of biosimilar candidate ABP 710 compared with REMICADE® (infliximab) in patients with moderate-to-severe rheumatoid arthritis. The results confirmed noninferiority compared to infliximab but could not rule out superiority based on its primary efficacy endpoint.
- In December 2018 and January 2019, we submitted a BLA to the FDA and a Marketing Authorization Application (MAA) to the EMA, respectively, for ABP 710.

ABP 798 (biosimilar rituximab)

- In January 2019, we and Allergan announced positive top-line results from a phase 1/phase 3 study evaluating the pharmacokinetics, efficacy and safety of ABP 798, a biosimilar candidate to RITUXAN® (rituximab), compared to rituximab in patients with moderate-to-severe rheumatoid arthritis. The results demonstrate that the study met its primary endpoint of pharmacokinetic similarity. Additionally, equivalent efficacy was established and a similar safety profile was demonstrated.

Next-generation biomanufacturing

- In April 2018, we announced plans to build a new next-generation biomanufacturing plant on our campus in West Greenwich, Rhode Island. The new plant will employ our next-generation biomanufacturing capabilities and manufacture products for the U.S. and global markets.

* FDA provisionally approved trade name.

Marketing, Distribution and Selected Marketed Products

The largest concentration of our sales and marketing forces is based in the United States and Europe. Additionally, we continue to expand the commercialization and marketing of our products into other geographic territories, including parts of Latin America, the Middle East and Asia. This expansion is occurring by establishing our own affiliates, by acquiring existing third-party businesses or product rights or by partnering with third parties. Whether we use our own sales and marketing forces or a third party's varies across these markets. Such use typically depends on several factors, including the nature of entry into the new market, the size of an opportunity and operational capabilities. Together with our partners, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies.

In the United States, we sell primarily to pharmaceutical wholesale distributors, which are the principal means of distributing our products to healthcare providers. We also market certain products through direct-to-consumer channels including, print, television and online media. For further discussion, see Government Regulation—Regulation in the United States—Regulation of Product Marketing and Promotion. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country.

Our product sales to three large wholesalers, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., each individually accounted for more than 10% of total revenues for each of the years ended December 31, 2018, 2017 and 2016. On a combined basis, these wholesalers accounted for 98%, 96% and 96% of our U.S. gross product sales for each of the years ended December 31, 2018, 2017 and 2016, respectively, and 84%, 81% and 81% of worldwide gross revenues for each of these years. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

Our products are marketed around the world, with the United States being our largest market. The following chart shows our product sales by principal product and by geography for the years ended 2018, 2017 and 2016.

Enbrel® (etanercept)

We market ENBREL primarily in the United States. It was launched in 1998 and is used primarily in indications for the treatment of adult patients with the following conditions:

- moderately to severely active rheumatoid arthritis;
- chronic moderate-to-severe plaque psoriasis patients who are candidates for systemic therapy or phototherapy; and
- active psoriatic arthritis.

Neulasta® (pegfilgrastim)

We market Neulasta®, a pegylated protein based on the filgrastim molecule, primarily in the United States and Europe. Neulasta® was launched in 2002 and is used primarily in the indication to help reduce the chance of infection due to a low white blood cell count, in patients with certain types of cancer (nonmyeloid) who receive anticancer medicines (chemotherapy) that can cause fever and a low blood cell count. In 2015, the Neulasta® Onpro® kit became available in the United States. The Neulasta® Onpro® kit provides physicians the opportunity to initiate the administration of Neulasta® on the same day as chemotherapy, with drug delivery of the recommended dose of Neulasta® at home the day after chemotherapy, thereby saving patients a trip back to the doctor.

Prolia® (denosumab)

We market Prolia® primarily in the United States and Europe. Prolia® contains the same active ingredient as XGEVA® (denosumab) but is approved for different indications, patient populations, doses and frequencies of administration. Prolia® was launched in the United States and Europe in 2010. In the United States, it is used primarily in the indication for the treatment of postmenopausal women with osteoporosis at high risk of fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In Europe, Prolia® is used primarily for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Aranesp® (darbepoetin alfa)

We market Aranesp® primarily in the United States and Europe. It was launched in 2001 and is indicated to treat a lower-than-normal number of red blood cells (anemia) caused by chronic kidney disease (CKD) (in both patients on dialysis and patients not on dialysis). Aranesp® is also indicated for the treatment of anemia due to concomitant myelosuppressive chemotherapy in certain patients with nonmyeloid malignancies and when chemotherapy will be used for at least two months after starting Aranesp®.

Aranesp® and EPOGEN® (epoetin alfa) compete with each other in the United States, primarily in the dialysis setting.

XGEVA®

We market XGEVA® primarily in the United States and Europe. XGEVA® was launched in the United States in 2010 and is now used primarily in the indication for the prevention of SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors and multiple myeloma. XGEVA® was launched in Europe in 2011 and is used primarily in the indication for the prevention of SREs in patients with bone metastases from solid tumors. It was approved in January 2018 in the United States and April 2018 in Europe for the prevention of SREs in patients with multiple myeloma.

Sensipar®/Mimpara® (cinacalcet)

We market cinacalcet as Sensipar® primarily in the United States and as Mimpara® primarily in Europe. It was launched in 2004 and is used primarily in the indication for the treatment of secondary hyperparathyroidism in adult patients with CKD who are on dialysis.

Sensipar® and our recently launched Parsabiv® (etelcalcetide) compete with each other.

EPOGEN®

We market EPOGEN® in the United States for dialysis patients. EPOGEN® was launched in 1989, and we market it for the indication to treat anemia caused by CKD in patients on dialysis in order to lessen the need for red blood cell transfusions. The majority of our sales are to a large dialysis provider.

Other Marketed Products

We also market a number of other products in various markets worldwide, including KYPROLIS® (carfilzomib), Nplate® (romiplostim), Vectibix® (panitumumab), Repatha® (evolocumab), NEUPOGEN® (filgrastim), Parsabiv®, BLINCYTO® (blinatumomab), Aimovig® (erenumab-aooe), IMLYGIC® (talimogene laherparepvec), Corlanor® (ivabradine), KANJINTI™ (biosimilar trastuzumab) and AMGEVITA™ (biosimilar adalimumab).

Patents

The following table lists our outstanding material patents for the indicated product by territory, general subject matter and latest expiry date. Certain of the European patents are the subjects of supplemental protection certificates that provide additional protection for the products in certain European countries beyond the dates listed in the table (see footnotes).

One or more patents with the same or earlier expiry date may fall under the same general subject matter and are not listed separately.

| Product | Territory | General subject matter | Expiration |
|---|---|---|---|
| Enbrel® (etanercept) | U.S. | Methods of treating psoriasis | 8/13/2019 |
| | U.S. | Aqueous formulation and methods of treatment using the formulation | 6/8/2023 |
| | U.S. | Fusion protein, and pharmaceutical compositions | 11/22/2028 |
| | U.S. | DNA encoding fusion protein, and methods of making fusion protein | 4/24/2029 |
| Prolia®/ XGEVA® (denosumab) | U.S. | RANKL antibodies | 9/17/2021 |
| | U.S. | Methods of treatment | 6/25/2022 |
| | U.S. | Nucleic acids encoding RANKL antibodies, and methods of producing RANKL antibodies | 11/30/2023 |
| | U.S. | RANKL antibodies including sequences | 2/19/2025 |
| | Europe | RANKL antibodies including epitope binding | 2/23/2021 |
| | Europe | RANKL antibodies including sequences[1] | 6/25/2022 |
| Aranesp® (darbepoetin alfa) | U.S. | Glycosylation analogs of erythropoietin proteins | 5/15/2024 |
| Sensipar®/ Mimpara® (cinacalcet) | U.S. | Formulation | 9/22/2026 |
| | Europe | Calcium receptor-active molecules[1] | 10/23/2015 |
| | Europe | Formulation | 9/10/2024 |
| KYPROLIS® (carfilzomib) | U.S. | Compositions and compounds | 12/7/2027 |
| | U.S. | Methods of treatment | 4/14/2025 |
| | U.S. | Methods of making | 5/8/2033 |
| | Europe | Compositions, compounds and methods of treatment[1] | 8/8/2025 |
| Nplate® (romiplostim) | U.S. | Thrombopoietic compounds | 1/19/2022 |
| | U.S. | Formulation | 2/12/2028 |
| | Europe | Thrombopoietic compounds[1] | 10/22/2019 |
| | Europe | Formulation | 4/20/2027 |
| Vectibix® (panitumumab) | U.S. | Human monoclonal antibodies to epidermal growth factor receptor | 4/8/2020 |
| | Europe | Human monoclonal antibodies to epidermal growth factor receptor[1] | 5/5/2018 |
| Repatha® (evolocumab) | U.S. | Antibodies[2] | 10/25/2029 |
| | U.S. | Methods of treatment | 10/8/2030 |
| | Europe | Compositions and method of treatment | 8/22/2028 |
| Parsabiv® (etelcalcetide) | U.S. | Compound and pharmaceutical composition[2] | 7/29/2030 |
| | U.S. | Formulation | 6/27/2034 |
| | Europe | Compound and pharmaceutical composition | 7/29/2030 |
| | Europe | Formulation | 6/27/2034 |
| BLINCYTO® (blinatumomab) | U.S. | Bifunctional polypeptides[2] | 4/21/2019 |
| | U.S. | Method of administration | 9/28/2027 |
| | Europe | Bifunctional polypeptides[1] | 11/26/2024 |
| | Europe | Method of administration | 11/29/2026 |
| Aimovig® (erenumab-aooe) | U.S. | CGRP receptor antibodies[2] | 11/9/2031 |

| | | | |
|---|---|---|---|
| | U.S. | Methods of treatment | 12/18/2029 |
| | Europe | CGRP receptor antibodies and methods of treatment | 12/18/2029 |
| IMLYGIC® (talimogene laherparepvec) | U.S. | Compositions | 11/23/2025 |
| | U.S. | Method of treatment | 3/27/2022 |
| | Europe | Composition and uses[(1)] | 3/27/2022 |
| Corlanor® (ivabradine) | U.S. | Crystalline forms | 2/22/2026 |

(1) A European patent with this subject matter may also be entitled to supplemental protection in one or more countries in Europe, and the length of any such extension will vary by country. For example, supplementary protection certificates have been issued related to the indicated products for patents in at least the following countries:

•denosumab — France, Italy, Spain and the United Kingdom, expiring in 2025
•cinacalcet — Germany expiring in 2019; France, Italy, Spain and the United Kingdom, expiring in 2020
•carfilzomib — France, Germany, Italy and Spain, expiring in 2030
•romiplostim — France, Germany, Italy, Spain and the United Kingdom, expiring in 2024
•panitumumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2022
•evolocumab — France and Spain, expiring in 2030
•blinatumomab — France, Italy and Spain, expiring in 2029
•erenumab — Italy expiring in 2033
•talimogene laherparepvec — Spain, expiring in 2026; France, Germany, Italy and the United Kingdom, expiring in 2027

(2) A patent with this subject matter may be entitled to patent term extension in the United States.

Competition

We operate in a highly competitive environment. A number of our marketed products are indicated in disease areas in which other products or treatments are currently available or are being pursued by our competitors through research and development (R&D) activities. Additionally, some competitor-marketed products target the same genetic pathways as our recently launched marketed products or are being pursued currently. This competition could impact the pricing and market share of our products. We continue to pursue ways to increase the value of our medicines through innovations during their life cycles, which can include expanding the disease areas for which our products are indicated and finding new methods to make the delivery of our medicines easier and less costly. Such activities can offer important opportunities for differentiation. For example, in 2015, we launched the Neulasta® Onpro® kit, which provides physicians the opportunity to initiate the administration of the recommended dose of Neulasta® on the same day as chemotherapy, with drug delivery at home the day after chemotherapy, thereby saving patients a trip back to the doctor. We also launched in 2017 the AutoTouch® reusable auto-injector to be used with Enbrel Mini® single-dose prefilled cartridges (50 mg/mL). The Enbrel Mini® utilizes a new drug formulation of ENBREL that was associated with statistically significant lower mean injection site pain than the current formulation. We plan to continue pursuing innovation efforts to strengthen our competitive position. Such position may be based on, among other things, safety, efficacy, reliability, availability, patient convenience/delivery devices, price, reimbursement, access to and timing of market entry and patent position and expiration.

Certain of the existing patents on our principal products have expired, and we face new and increasing competition, including from biosimilars and generics. We may also compete against biosimilar or generic versions of our competitors' products. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "highly similar" to the original reference product. We expect that the adverse impact on our product sales from biosimilar competition will be more like branded biologic competition than that seen when branded small molecules face generics, but we believe that when multiple biosimilar versions of one of our products get approved and launched, competition could intensify more rapidly, resulting in a greater impact on our product's sales. Although we expect biosimilars to compete on price, we believe many patients, providers and payers will continue to place high value on the reputation, reliability and safety of our products. In the United States, companies now have approved biosimilar versions of EPOGEN®, NEUPOGEN®, Neulasta® and ENBREL. See also Government Regulation—Regulation in the United States—Approval of Biosimilars. As biosimilar competitors come to market, we will leverage both the experience we have had in the United States versus branded competition and our experience in competing against epoetin alfa and filgrastim biosimilars in Europe. In addition, although most of our products are biologics, some of our products are small-molecule products. Because the FDA approval process allows generic manufacturers to rely on the safety and efficacy data of the innovator product rather than having to conduct their own costly and time-consuming clinical trials, generic manufacturers can often market their competing versions of our small-molecule products at much lower prices. As a result, upon the expiration or loss of patent protection for a small-molecule product, we can lose the majority of revenues for that product in a very short

period of time.

The introduction of new products, the development of new processes or technologies by competitors or the emergence of new information about existing products may result in increased competition for our marketed products, even for those protected by patents, or in reductions in the prices we receive from selling our products. In addition, the development of new treatment options or standards of care may reduce the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates. (As used in this document, the term clinical trials may include prospective clinical trials, observational studies, registries and other studies.) See Item 1A. Risk Factors—Our products face substantial competition and Item 1A. Risk Factors—We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.

The following table reflects our significant competitors and is not exhaustive.

| Product | Territory | Competitor-marketed product | Competitors |
|---|---|---|---|
| ENBREL | U.S. & Canada | REMICADE®* | Janssen Biotech, Inc. (Janssen)[1] |
| | U.S. & Canada | HUMIRA® | AbbVie Inc. |
| | U.S. & Canada | STELARA®[2] | Janssen[1] |
| | U.S. & Canada | Otezla®[2] | Celgene Corporation (Celgene) |
| Neulasta®[3] | U.S. | UDENYCA™ | Coherus BioSciences, Inc. |
| | U.S. | Fulphila® | Mylan Institutional Inc. |
| | U.S. & Europe | Filgrastim biosimilars | Various |
| Prolia® | U.S. & Europe | Alendronate, raloxifene and zoledronate generics | Various |
| Aranesp® | U.S. | PROCRIT®[4] | Janssen[1] |
| | U.S. | MIRCERA®[5] | Galenica Group (Galenica)/F. Hoffmann-La Roche Ltd. (Roche) |
| | U.S. & Europe | Epoetin alfa biosimilars | Various |
| XGEVA® | U.S. & Europe | Zoledronate generics | Various |
| Sensipar®[6]/ Mimpara® | U.S. & Europe | Active vitamin D analogs | Various |
| EPOGEN®[3] | U.S. | MIRCERA®[5] | Galenica/Roche |
| | U.S. | RETACRIT™ | Hospira[7] |
| KYPROLIS®[9] | U.S. | VELCADE® | Millennium Pharmaceuticals, Inc.[8] |
| | U.S. | REVLIMID® | Celgene |
| | U.S. | POMALYST® | Celgene |
| | U.S. | DARZALEX® | Janssen[1] |
| Repatha® | U.S. & Europe | PRALUENT® | Regeneron<br>Sanofi |
| Parsabiv® | U.S. & Europe | Active vitamin D analogs | Various |
| Aimovig® | U.S. | AJOVY™ | Teva Pharmaceuticals USA, Inc. |
| | U.S. | Emgality™ | Eli Lilly and Company |

* Approved biosimilars available.

(1) A subsidiary of Johnson & Johnson (J&J).

(2) Dermatology only.

(3) Other biosimilars under regulatory review in the United States and Europe.

(4) PROCRIT® competes with Aranesp® in the supportive cancer care and predialysis settings.

(5) MIRCERA® competes with Aranesp® only in the nephrology segment.

(6) Our U.S. composition of matter patent for Sensipar® expired in March 2018. We are engaged in litigation with a number of companies seeking to market generic versions of Sensipar® surrounding our U.S. formulation patent that expires in September 2026. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements, for further information. Several of these generic versions of Sensipar® have been approved by the FDA.

(7) A subsidiary of Pfizer Inc. (Pfizer)

(8) A subsidiary of Takeda Pharmaceutical Company Limited.
(9) KYPROLIS® is facing increased competition from several recently approved products.

Reimbursement

Sales of our principal products are dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, including government health systems, private health insurers and other organizations, remain focused on reducing the cost of healthcare, and their efforts have intensified as a result of rising healthcare costs and economic challenges. Drugs, and in particular specialty drugs such as our products, remain heavily scrutinized for cost containment. As a result, payers are becoming more restrictive regarding the use of biopharmaceutical products and scrutinizing the prices of these products, while requiring a higher level of clinical evidence to support the benefit such products bring to patients and the broader healthcare system. These pressures are intensified where our products are subject to increasing competition.

In the United States, healthcare providers and other entities such as pharmacies and Pharmacy Benefit Managers (PBMs) are reimbursed for covered services and products they deliver through Medicare, Medicaid and other government healthcare programs, as well as through private payers. We are required to provide rebates or discounts on our products that are reimbursed through certain government programs, including Medicare and Medicaid, and also provide discounts to qualifying healthcare providers under the Federal 340B Drug Pricing Program. In addition, we provide rebates to PBMs, as well as other entities (such as hospitals and pharmacies), which are payments by a biopharmaceutical manufacturer of a portion of the product's purchase price back to the PBMs or other entities. Biopharmaceutical-product pricing remains central to discussions on controlling healthcare costs in the United States. Policy makers from both of the major U.S. political parties are pursuing policies to lower drug costs for patients. In May 2018, U.S. president Donald Trump and his administration released a drug-pricing "blueprint" and requested public comment on an array of policy ideas intended to increase competition, improve the federal government's negotiating power, reduce drug prices and lower patients' out-of-pocket costs. The blueprint included a number of policy ideas with the potential to significantly affect, whether individually or collectively, the biopharmaceutical industry; and the U.S. presidential administration has already begun to implement certain elements described in the administration's drug-pricing blueprint, such as (i) seeking initial feedback on a potential program that would set the Medicare payment amount for Part B single-source drugs and biologics to be more closely aligned with international drug prices and rely on third-party vendors, (ii) issuing guidance to allow certain Medicare plans offered by private insurance companies to begin requiring that patients receiving Medicare Part B drugs first try a drug preferred by the plan before such plan will cover another therapy, (iii) lowering initial reimbursement rates for new Part B drugs launched beginning in 2019 and (iv) proposing new rules to require drug price information in direct-to-consumer drug television advertising. The blueprint also discussed (i) the potential removal of the safe-harbor protection under the federal anti-kickback statute for drug rebates paid to payers and (ii) changes to the Part D program. At the same time, value assessments of new technologies previously used predominantly outside the United States are having an impact in the U.S. healthcare environment. Healthcare provider organizations and independent organizations are creating their own value assessments of biopharmaceutical drugs for comparison with manufacturer pricing. Although these organizations do not set drug prices, they seek to influence pricing as well as payer and provider decision making by publicly disclosing their assessments, often making assertions around what they believe to be the appropriate price to charge for a product. In addition, continued consolidation of payers and integration of providers and payers (integrated delivery systems) increase the level of market power held by our customers. Such developments, particularly when taken in combination with increasing product competition, put greater pressure on access to, pricing of and sales of our products.

In addition, rebates and/or discount levels as well as the number of entities that are entitled to receive them since they are reimbursed through government programs have increased over time. For example, the Bipartisan Budget Act, enacted in 2018, requires biopharmaceutical manufacturers to pay greater discounts for patients in the Medicare Part D coverage gap beginning in 2019; and the Patient Protection and Affordable Care Act (ACA), enacted in 2010, increased many of the mandatory discounts and rebates required of us. The ACA also imposed a new Branded Prescription Pharmaceutical Manufacturers and Importers fee payable each year by us and other manufacturers. In the Tax Cuts and Jobs Act (2017 Tax Act) signed by President Trump in December 2017, Congress removed a key ACA provision by repealing the individual mandate penalty, which required every person to have health insurance or pay a penalty. Future changes to government programs such as the ACA, whether legislative or regulatory, could impact the

number of patient lives covered, could raise or lower the cost or quality of insurance, could affect Medicaid eligibility and could change levels of patient protections provided unless alternatives are put in place.

Other government legislative and regulatory actions that would have a significant impact on Amgen include changes to how the Medicare program covers and reimburses current and future drugs, including for patients with end-stage renal disease (ESRD); changes in the federal payment rate or new rebate requirements for covered drugs and policies for drug payment in Medicare or Medicaid; and changes to coverage and payment for biosimilars, such as policies that would facilitate easier substitution for, or provide reimbursement advantages over, the corresponding innovative products. In ESRD, the Centers for Medicare & Medicaid Services (CMS) uses a bundled-payment system and recently finalized changes allowing more new dialysis drugs to be eligible for temporary add-on payment adjustments starting in 2020. Sensipar® and Parsabiv® were already eligible for add-on payment adjustments beginning in 2018 and will continue to receive them in 2019. CMS has indicated interest in testing new models for drug payment in Medicare Part B and Part D. CMS also continues to test alternative payment models with providers, such as the

Oncology Care Model. These models provide financial incentives for providers who participate; under the models, providers take on greater risk for the overall cost and quality of care. In addition, in 2018 CMS implemented changes to Medicare payment to hospitals for Part B drugs acquired through the Federal 340B Drug Pricing Program but provided a financial incentive for hospitals to use biosimilar products over the corresponding innovative products. As described above, CMS is permitting Medicare Advantage plans to implement access controls for Part B drugs while also (i) considering a proposal that would set the Medicare payment amount for Part B single-source drugs and biologics to more closely align with international drug prices and rely on third-party vendors and (ii) considering changes to Medicare Part D and Medicare Advantage. These and/or other changes have the potential to impact prescribing and patient access to Amgen's therapies.

Additional efforts by state legislatures and government agencies in the United States could also affect us and our industry. For example, a California law requires manufacturers to provide payers advance notice of a price increase over a specified threshold, and laws in Oregon and Vermont require manufacturers to submit price increase justifications to a state attorney agency if certain price increase and state-spending thresholds are met. Examples of other proposals that have been discussed and debated but not yet enacted include state ballot initiatives that would place a maximum price ceiling, or cap, on pharmaceutical products purchased by state agencies and state legislative efforts to cap pharmaceutical prices for commercial payers.

In the U.S. private sector, payers continue to institute cost reduction and containment measures that lower drug utilization and/or spending altogether and/or shift a greater portion of the costs to patients. Such measures include more limited benefit plan designs, higher patient co-pays or coinsurance obligations, limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs), stricter utilization management criteria before a patient may get access to a drug, and/or higher-tier formulary placement that increases the level of patient out-of-pocket costs. The use of such measures by PBMs and insurers that handle the majority of sales for ENBREL and Repatha® has continued to intensify and thereby limited Amgen product usage and sales. Consolidation has resulted in a smaller number of PBMs and insurers overseeing a large portion of total covered lives in the United States. As a result, PBMs and insurers have greater market power and negotiating leverage to mandate stricter utilization criteria and/or exclude drugs from their formularies in favor of competitor drugs or alternative treatments. Our past experience with Repatha® underscores that utilization management requirements, including the burdensome administrative processes required of physicians to demonstrate and document that patients meet such requirements, continue to be a significant challenge for patients and physicians, limiting access for appropriate usage. Formulary exclusion effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. A drug's inclusion and favorable positioning on formulary is essential to ensure patients have access. Even when access is available, some patients abandon their prescriptions due to economic reasons. In highly competitive treatment markets such as with ENBREL, Repatha® and Aimovig®, PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order to maintain their formulary position.

In many countries outside the United States, government-sponsored healthcare systems are the primary payers for drugs and biologics. With increasing budgetary constraints, and/or difficulty in understanding the value of medicines, governments and payers in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls; price referencing; therapeutic-reference pricing; increases in mandates; incentives for generic substitution and biosimilar usage; and government-mandated price cuts. In this regard, many countries have health technology assessment organizations that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies, and these organizations are expanding in established and emerging markets. We expect that countries will continue to take aggressive actions to seek to reduce expenditures on drugs and biologics. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

The dynamics and developments discussed above serve to create pressure on the pricing and potential usage of our products and the industry. We remain focused on delivering breakthrough treatments for unmet medical needs. Amgen is committed to working with the entire healthcare community to ensure continued innovation and to facilitate patient access to needed medicines. We do this by:

- investing billions of dollars annually in R&D;
- developing more affordable therapeutic choices in the form of high-quality and reliably-supplied biosimilars;
- pricing our medicines to reflect the value they provide;
- partnering with payers to share risk and accountability for health outcomes;
- providing patient support and education programs and helping patients in financial need access our medicines; and
- working with policy makers, patients and other stakeholders to establish a sustainable healthcare system with access to affordable care and where patients and their healthcare professionals are the primary decision makers.

See Item 1A. Risk Factors—Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability and Item 1A. Risk Factors—Guidelines and recommendations published by various organizations can reduce the use of our products.

Manufacturing, Distribution and Raw Materials

Manufacturing

We believe we are a leader in the manufacturing of biologics and that our manufacturing capabilities represent a competitive advantage. The products we manufacture consist of both biologics and small-molecule drugs. The majority of our products are biologics that are produced in living cells and that are inherently complex due to naturally-occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Further, our expertise in manufacturing of biologics positions us well for leadership in the global biosimilars market. For additional information regarding manufacturing facilities, see Item 2. Properties.

Our internal manufacturing network has the commercial production capabilities of bulk manufacturing, formulation, fill, finish and device assembly. These activities are performed within the United States and its territories in our Puerto Rico, Rhode Island and California facilities as well as internationally in our Ireland, Netherlands and Singapore facilities. In addition, we utilize third-party contract manufacturers to supplement the capacity or capability of our commercial manufacturing network.

To support our clinical trials, we manufacture product candidates primarily at our California and, to a lesser extent, our Rhode Island facilities. We also utilize third-party contract manufacturers for certain clinical products.

See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

Distribution

We operate distribution centers in Puerto Rico, Kentucky, California and the Netherlands for worldwide distribution of the majority of our commercial and clinical products. We also use third-party distributors to supplement distribution of our products worldwide.

Other

In addition to the manufacturing and distribution activities noted above, each of our manufacturing locations also includes key manufacturing support functions, including quality control, process development, procurement, production scheduling and warehousing. Certain of those manufacturing and distribution activities are highly regulated by the FDA as well as other international regulatory agencies. See Government Regulation—Regulation in the United States—Regulation of Manufacturing Standards.

Manufacturing Initiatives

We have multiple ongoing initiatives that are designed to extend our manufacturing advantage by optimizing our manufacturing network and/or mitigating risks while continuing to ensure adequate supply of our products.

In 2017, our next-generation biomanufacturing plant in Singapore was licensed by the FDA and the EMA for certain commercial-scale production. In 2018, we successfully completed additional bulk process qualification campaigns, which if approved, would permit the commercial production of an additional product at that site. A next-generation biomanufacturing plant incorporates multiple innovative technologies into a single facility and therefore can be built in half the construction time with approximately one-half of the operating cost of a traditional plant. Next-generation biomanufacturing plants require a smaller manufacturing footprint and offer greater environmental benefits, including reduced consumption of water and energy and lower levels of carbon emissions. Within the plant, the equipment is portable and smaller, and some components are disposable, which provides greater flexibility and speed when manufacturing different medicines simultaneously. This eliminates costly and complex retrofitting inherent in standard plants and allows Amgen to respond to changing demands for its medicines with increased agility, ultimately impacting the speed at which a medicine is available for patients. The Singapore site also has a plant with the capability to produce small-molecule drugs. When approved by relevant regulatory authorities this plant can be used for commercial manufacturing.

In July 2018, we announced the groundbreaking of our new next-generation biomanufacturing plant that will be constructed at our West Greenwich, Rhode Island, campus. The new plant is expected to be the first of its kind in the

United States and will use our next-generation biomanufacturing capabilities. After construction has been completed and upon approval by the FDA and other global regulatory authorities, this plant will expand our capacity to manufacture certain products for U.S. and global markets.

See Item 1A. Risk Factors—Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Raw Materials and Medical Devices

Certain raw materials, medical devices (including companion diagnostics) and components necessary for the commercial and/or clinical manufacturing of our products are provided by and are the proprietary products of unaffiliated third-party suppliers, certain of which may be our only sources for such materials. We currently attempt to manage the risk associated with such suppliers by inventory management, relationship management and evaluation of alternative sources when feasible. We also monitor the financial condition of certain suppliers and their ability to supply our needs. See Item 1A. Risk Factors—We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We perform various procedures to help authenticate the source of raw materials, including intermediary materials used in the manufacture of our products, which include verification of the country of origin. The procedures are incorporated into the manufacturing processes we and our third-party contract manufacturers perform.

Government Regulation

Regulation by government authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities. In order to clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. Compliance with these standards is complex, and failure to comply with any of these standards can result in significant implications. See Item 1A. Risk Factors for a discussion of factors, including global regulatory implications, that can adversely impact our development and marketing of commercial products.

Regulation in the United States

In the United States, the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act (FDCA) and the regulations promulgated thereunder, as well as other federal and state statutes and regulations govern, among other things, the production, research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising, promotion and distribution of our products, as well as the reporting of certain payments and other transfers of value to healthcare professionals and teaching hospitals.

Clinical Development and Product Approval. Drug development in our industry is complex, challenging and risky; and failure rates are high. Product development cycles are typically very long—approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable risk-benefit profile.

After laboratory analysis and preclinical testing in animals, we file an Investigational New Drug Application (IND) with the FDA to begin human testing. Typically, we undertake an FDA-designated three-phase human clinical testing program.

- In phase 1, we conduct small clinical trials to investigate the safety and proper dose ranges of our product candidates in a small number of human subjects.
- In phase 2, we conduct clinical trials to investigate side-effect profiles and the efficacy of our product candidates in a large number of patients who have the disease or condition under study.
- In phase 3, we conduct clinical trials to investigate the safety and efficacy of our product candidates in a large number of patients who have the disease or condition under study.

The FDA monitors the progress of each trial conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate the testing based on the data accumulated to that point and the FDA's risk-benefit assessment with regard to the patients enrolled in the trial. The results of preclinical and clinical trials are submitted to the FDA in the form of either a BLA for biologic products or a New Drug Application for small-molecule products. We are not permitted to market or promote a new product until the FDA has approved our marketing application.

Approval of Biosimilars. The ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the nonclinical and clinical trial data of an originator product to which the biosimilar has been demonstrated to be "highly similar" and to have no clinically meaningful differences in terms of safety, purity and potency. The relevance of demonstrating "similarity" is that in many cases, biosimilars can be brought to market without conducting the full suite of clinical trials typically required of originators, as risk-benefit has previously been established. In order to preserve incentives for future innovation, the law establishes a period of exclusivity for originators' products, which in general prohibits

biosimilars from gaining FDA approval based in part on reliance on or reference to the originator's data in their application to the FDA for 12 years after initial FDA approval of the originator product. The law does not change the duration of patents granted on biologic products. The FDA has released a number of guidance documents as part of the implementation of the abbreviated approval pathway for biosimilars, some of which remain in draft form.

As of the end of 2018, 16 biosimilar applications have been approved by the FDA, including our products AMJEVITA™, a biosimilar candidate to HUMIRA® (adalimumab), and MVASI™, a biosimilar candidate to Avastin® (bevacizumab), as well as competitors to our products ENBREL, Aranesp®, EPOGEN®, NEUPOGEN® and Neulasta®. A number of manufacturers have announced the filing of marketing applications to the FDA under the biosimilar pathway, some of which are for biosimilars of our products.

Regulation of Product Marketing and Promotion. The FDA regulates the marketing and promotion of drug products. Our product promotion for approved product indications must comply with the statutory standards of the FDCA and the FDA's implementing regulations and guidance. The FDA's review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare-provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with the FDA's regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Additionally, as described below, such failure may lead to additional liability under U.S. health care fraud and abuse laws.

Regulation of Manufacturing Standards. The FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to providing approval to market products. If after receiving approval from the FDA we make a material change in manufacturing equipment, location or process, additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA conducts regular, periodic visits to reinspect our equipment, facilities, laboratories and processes following an initial approval.

Regulation of Combination Products. Combination products are defined by the FDA to include products composed of two or more regulated components (e.g., a biologic and/or drug and a device). Biologics/drugs and devices each have their own regulatory requirements, and combination products may have additional requirements. A number of our marketed products meet this definition and are regulated under this framework, and we expect that a number of our pipeline product candidates will be evaluated for regulatory approval under this framework as well.

Regulation outside the United States

In the European Union (EU) countries as well as Switzerland, Canada, Australia and Japan, regulatory requirements and approval processes are similar in principle to those in the United States.

In the EU, there are currently two potential tracks for seeking marketing approval for a product not authorized in any EU member state: a decentralized procedure and a centralized procedure. In the decentralized procedure, identical applications for marketing authorization are submitted simultaneously to the national regulatory agencies. Regulatory review is led by one member state (the reference-member state), and its assessment—based on safety, quality and efficacy—is reviewed and approved (assuming there are no concerns that the product poses a serious risk to public health) by the other member states from which the applicant is seeking approval (the concerned-member states). The decentralized procedure leads to a series of single national approvals in all relevant countries. In the centralized procedure, which is required of all products derived from biotechnology, a company submits a single MAA to the EMA, which conducts an evaluation of the dossier, drawing upon its scientific resources across Europe. If the drug product is proven to fulfill the requirements for quality, safety and efficacy, the EMA's CHMP adopts a positive opinion, which is transmitted to the EC for final decision on grant of the marketing authorization. While the EC generally follows the CHMP's opinion, it is not bound to do so. Subsequent commercialization is enabled by country-by-country reimbursement approval.

In the EU, biosimilars are approved under a specialized pathway of the centralized procedure. As with the U.S. pathway, applicants seek and obtain regulatory approval for a biosimilar once the data exclusivity period for the original reference product has expired relying in part on the data submitted for the originator product together with

data evidencing that the biosimilar is “highly similar” in terms of quality, safety and efficacy to the original reference product authorized in the European Economic Area.

As a result of the United Kingdom’s vote to leave the EU in March 2019, the EMA announced that it will relocate its headquarters from London to Amsterdam by March 30, 2019. While negotiations continue regarding the terms of the United Kingdom’s withdrawal from the EU, the specific impact to the supervision, regulation and supply of medicines in the United Kingdom and Europe remain unclear.

Other countries such as Russia, Turkey and those in Latin America and the Middle East have review processes and data requirements similar to those of the EU and in some cases can rely on prior marketing approval from U.S. or EU regulatory authorities. The regulatory process in these countries may include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements.

In Asia Pacific, a number of countries such as China, Japan, South Korea and Taiwan may require local clinical trial data for bridging purposes as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. In most of the Asian markets, registration timelines depend on marketing approval in the United States or the EU. In some markets in Asia, such as China, Thailand and Indonesia, the regulatory timelines can be less predictable. The regulatory process may also include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Countries such as Australia and Japan have more mature systems that would allow for submissions in more competitive time frames. Regarding biosimilars, several of these countries have pathways to register biosimilars (e.g., South Korea, India, Australia, Singapore and Taiwan), and biosimilar products are already present on the markets (e.g., Australia and South Korea).

In some countries, such as Japan and those in the EU, medical devices may be subject to regulatory regimes whereby the manufacturer must establish that its medical device conforms to essential requirements set out in the law for the particular device category. For example, in the EU, with limited exceptions, medical devices placed on the market must bear the Conformité Européenne marking to indicate their conformity with legal requirements.

Post-approval Phase

After approval, we continue to monitor adverse events and product complaints reported following the use of our products through routine post-marketing surveillance and studies when applicable. We report such events to the appropriate regulatory agencies as required per local regulations for individual cases and aggregate reports. We proactively monitor (according to good pharmacovigilance practices) and ensure implementation of signal detection, assessment and the communication of adverse events that may be associated with the use of our products. We also proactively monitor product complaints through our quality systems, which includes assessing our drug delivery devices for device complaints, adverse events and malfunctions. We may also be required by regulatory agencies to conduct further clinical trials on our marketed products as a condition of their approval or to provide additional information on safety and efficacy. Health authorities, including the FDA, have authority to mandate labeling changes to products at any point in a product's lifecycle based on new safety information or as part of an evolving label change to a particular class of products.

Health authorities, including the FDA, also have the authority, before or after approval, to require companies to implement a risk management program for a product to ensure that the benefits of the drug outweigh the risks. Each risk management program is unique and varies depending on the specific factors required. In the United States, a risk management program is known as a risk evaluation and mitigation strategy (REMS) and we currently have REMS for Prolia®, Nplate® and BLINCYTO®.

Other Regulation

We are also subject to various laws pertaining to healthcare fraud and abuse, including anti-kickback laws and false-claims laws. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescribing of a particular drug that is reimbursed by a state or federal program. False-claims laws prohibit knowingly and willingly presenting or causing to be presented for payment to third-party payers (including Medicare and Medicaid), any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as by the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). Liability under the false-claims laws may also arise when a violation of certain laws or regulations related to the underlying products (e.g., violations regarding improper promotional activity or unlawful payments) contributes to the submission of a false claim.

In 2012, Amgen entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services, which was formally closed out in August 2018. Due to the breadth of the

statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that in the future our practices might be further challenged under anti-kickback or similar laws. Additionally, the U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Our business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

Research and Development and Selected Product Candidates

We focus our R&D on novel human therapeutics for the treatment of serious illness. We capitalize on our strength in human genetics, novel biology and protein engineering. We leverage our biologic expertise and take a modality-independent approach to R&D. We use cutting-edge science and technology to study subtle biological mechanisms in search of therapies that will improve the lives of those who suffer from diseases. Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, other combination modalities or new modalities. Leveraging two decades of research at deCODE, a global leader in analyzing the human genome, we are reshaping our portfolio and increasingly focusing efforts on validated targets. Human genetic validation is used whenever possible in order to enhance the likelihood of success. For the years ended December 31, 2018, 2017 and 2016, our R&D expenses were $3.7 billion, $3.6 billion and $3.8 billion, respectively.

We have major R&D centers in Thousand Oaks and San Francisco, California; Cambridge, Massachusetts; Iceland; and the United Kingdom, as well as smaller research centers and development facilities globally. See Item 2. Properties.

Our clinical trial activities are conducted by both our internal staff and third-party contract clinical trial service providers. To increase the number of patients available for enrollment in our clinical trials, we have opened clinical sites and will continue opening clinical sites and enrolling patients in a number of geographic locations. See Government Regulation—Regulation in the United States—Clinical Development and Product Approval for a discussion of government regulation over clinical development. Also see Item 1A. Risk Factors—We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.

Some of our competitors are actively engaged in R&D in areas in which we have products or in which we are developing product candidates or new indications for existing products. For example, we compete with other clinical trials for eligible patients, which may limit the number of available patients who meet the criteria for certain clinical trials. The competitive marketplace for our product candidates is greatly dependent on the timing of entry into the market. Early entry may have important advantages in gaining product acceptance, thereby contributing to a product's eventual success and profitability. Accordingly, we expect that in some cases, the relative speed with which we can develop products, complete clinical testing, receive regulatory approval and supply commercial quantities of a product to the market will be important to our competitive position.

In addition to product candidates and marketed products generated from our internal R&D efforts, we acquire companies, acquire and license certain product and R&D technology rights and establish R&D arrangements with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. In pursuing these R&D arrangements and licensing or acquisition activities, we face competition from other pharmaceutical and biotechnology companies that also seek to license or acquire technologies, product candidates or marketed products from those entities performing the R&D.

The following table shows a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 12, 2019, unless otherwise indicated. Additional product candidate information can be found on our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.) The information in this section does not include other, nonregistrational clinical trials that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication.

We may conduct nonregistrational clinical trials for various reasons, including to evaluate real-world outcomes or to collect additional safety information with regard to the use of our products. In addition, the table does not include biosimilar products we are developing, which are discussed later in this section.

| Molecule | Disease/condition |
|---|---|
| Phase 3 Programs | |
| ENBREL | Rheumatoid arthritis remission |
| EVENITY™ | Postmenopausal osteoporosis; Male osteoporosis |
| IMLYGIC® | Metastatic melanoma |
| KYPROLIS® | Multiple myeloma |
| Omecamtiv mecarbil | Chronic heart failure |
| Tezepelumab | Severe asthma |
| AMG 520 / CNP520 | Alzheimer's disease |
| Phase 2 Programs | |
| BLINCYTO® | Diffuse large B-cell lymphoma |
| Tezepelumab | Atopic dermatitis |
| AMG 714 / PRV-015 | Celiac disease |
| Phase 1 Programs | |
| IMLYGIC® | Various cancer types |
| AMG 119 | Small-cell lung cancer |
| AMG 160 | Prostate cancer |
| AMG 176 | Hematologic malignancies |
| AMG 212 | Prostate cancer |
| AMG 330 | Acute myeloid leukemia |
| AMG 397 | Hematologic malignancies |
| AMG 420 | Multiple myeloma |
| AMG 424 | Multiple myeloma |
| AMG 427 | Acute myeloid leukemia |
| AMG 510 | Solid tumors |
| AMG 562 | Non-Hodgkin's lymphoma |
| AMG 570 | Systemic lupus erythematosus |
| AMG 592 | Inflammatory diseases |
| AMG 596 | Glioblastoma |
| AMG 598 | Obesity |
| AMG 673 | Acute myeloid leukemia |
| AMG 701 | Multiple myeloma |
| AMG 757 | Small-cell lung cancer |
| AMG 890 | Cardiovascular disease |
| AMG 966 | Inflammatory bowel diseases (Crohn's and ulcerative colitis) |
| AMG 986 | Heart failure |

| | |
|---|---|
| Phase 3 | Clinical trials investigate the safety and efficacy of product candidates in a large number of patients who have the disease or condition under study; typically performed with registrational intent. |
| Phase 2 | Clinical trials investigate side effect profiles and efficacy of product candidates in a large number of patients who have the disease or condition under study. |
| Phase 1 | Clinical trials investigate the safety and proper dose ranges of product candidates in a small number of human subjects. |

Phase 3 Product Candidate Program Changes

As of February 12, 2018, we had 13 phase 3 programs. As of February 12, 2019, we had eight phase 3 programs, as regulatory approvals were received for three programs, and two programs concluded. These changes are set forth in the following table.

| Molecule | Disease/condition | Program change |
|---|---|---|
| Aimovig® | Migraine prevention | BLA approved by FDA |
| Aranesp® | Myelodysplastic syndromes | Concluded; no longer pursuing our marketing application with the EC |
| BLINCYTO® | ALL | sBLA approved by FDA |
| ENBREL | Psoriatic arthritis | Concluded; study achieved its primary endpoint |
| Prolia® | Glucocorticoid-induced osteoporosis | sBLA approved by FDA and EC |

Phase 3 Product Candidate Patent Information

The following table describes our outstanding composition of matter patents that have been issued thus far for our product candidates in phase 3 development that have yet to be approved for any indication in the United States or the EU. Patents for products already approved for one or more indications in the United States or the EU but that are currently undergoing phase 3 clinical trials for additional indications are previously described. See Marketing, Distribution and Selected Marketed Products—Patents.

| Molecule | Territory | General subject matter | Estimated expiration* |
|---|---|---|---|
| EVENITY™ | U.S. | Polypeptides | 2026 |
| | Europe | Polypeptides | 2026 |
| Omecamtiv mecarbil | U.S. | Compound | 2027 |
| | Europe | Compound | 2025 |
| Tezepelumab | U.S. | Polypeptides | 2029 |
| | Europe | Polypeptides | 2028 |
| AMG 520 / CNP520 | U.S. | Compound | 2032 |
| | Europe | Compound | 2032 |

* Patent expiration estimates are based on issued patents, which may be challenged, invalidated or circumvented by competitors. The patent expiration estimates do not include any term adjustments, extensions or supplemental protection certificates that may be obtained in the future and extend these dates. Corresponding patent applications are pending in other jurisdictions. Additional patents may be filed or issued and may provide additional exclusivity for the product candidate or its use.

Phase 3 and 2 Program Descriptions

The following provides additional information about selected product candidates that have advanced into human clinical trials.

BLINCYTO®

BLINCYTO® is an anti-CD19 x anti-CD3 (BiTE®) bispecific antibody construct.

A phase 2/3 study in patients with relapsed or refractory diffuse large B-cell lymphoma is ongoing.

ENBREL

ENBREL is a fusion protein that inhibits tumor necrosis factor.

A phase 3 study to evaluate ENBREL as a monotherapy in maintaining remission in rheumatoid arthritis is ongoing.

EVENITY™

EVENITY™ is a humanized monoclonal antibody that inhibits the action of sclerostin. It is being evaluated as a treatment for osteoporosis. EVENITY™ is being developed in collaboration with UCB.

In January 2019, we and UCB announced support from the FDA BRUDAC for the approval of EVENITY™ for the treatment of postmenopausal women with osteoporosis at high risk for fracture. Also in January 2019, the Japanese Ministry of Health, Labor and Welfare granted a marketing authorization for EVENITY™ for the treatment of osteoporosis in men and postmenopausal women at high risk of fracture.

IMLYGIC®

IMLYGIC® is an oncolytic immunotherapy derived from herpes simplex virus type 1.

A phase 1b/3 study to evaluate IMLYGIC® in combination with Merck & Company, Inc.'s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with mid- to late-stage metastatic melanoma is ongoing.

KYPROLIS®

KYPROLIS® is a proteasome inhibitor.

In April 2018, we announced that the CHMP of the EMA adopted a positive opinion recommending a label variation for KYPROLIS® to include the final overall survival data from the phase 3 ASPIRE study.

In June 2018, we announced that the FDA approved the sNDA to add the positive overall survival data from the phase 3 ASPIRE study to the U.S. Prescribing Information for KYPROLIS® in patients with relapsed or refractory multiple myeloma.

In October 2018, we announced that the FDA approved the sNDA to expand the Prescribing Information for KYPROLIS® to include a once-weekly dosing option in combination with dexamethasone for patients with relapsed or refractory multiple myeloma.

A phase 3 study comparing carfilzomib, dexamethasone, and daratumumab to carfilzomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma is ongoing.

Omecamtiv mecarbil

Omecamtiv mecarbil is a small-molecule activator of cardiac myosin. It is being evaluated for the treatment of chronic heart failure. Omecamtiv mecarbil is being developed by Amgen in collaboration with Cytokinetics, Inc., and in collaboration with Servier for certain territories.

A phase 3 cardiovascular outcomes study for the treatment of chronic heart failure is ongoing.

Tezepelumab

Tezepelumab is a human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin. It is being evaluated as a treatment for severe asthma in an ongoing phase 3 study, as well as atopic dermatitis. Tezepelumab is being developed jointly in collaboration with AstraZeneca.

AMG 520 / CNP520

AMG 520 / CNP520 is a small-molecule inhibitor of beta-site amyloid precursor protein-cleaving enzyme-1 (BACE). It is being evaluated for the prevention of Alzheimer's disease, with phase 3 studies ongoing. AMG 520 / CNP520 is being developed jointly in collaboration with Novartis.

AMG 714 / PRV-015

AMG 714 / PRV-015 is a human monoclonal antibody that binds to Interleukin-15. It is being investigated for the treatment of celiac disease. In November 2017, Amgen reacquired the AMG 714 program from Celimmune LLC. AMG 714 / PRV-015 is being developed jointly in collaboration with Provention Bio.

Amgen Development of Biosimilars

We also develop and commercialize biosimilar medicines. Our biosimilar product candidates in late-stage clinical development are described in the following table:

| Program | Reference product | Status |
|---|---|---|
| ABP 710 | Infliximab (REMICADE®) | Filed BLA with the FDA and MAA with the EMA |
| ABP 798 | Rituximab (Rituxan® / Mabthera®) | Phase 3 rheumatoid arthritis study completed<br>Phase 3 non-Hodgkin's lymphoma study ongoing |
| ABP 959 | Eculizumab (Soliris®) | Phase 3 initiated |

In addition to the above programs, AMJEVITA™ / AMGEVITA™ and MVASI™ have been approved by the FDA and the EC. KANJINTI™ has been approved by the EC and we have refiled our BLA with the FDA. We are also pursuing other biosimilar product candidates in earlier-stage development.

Business Relationships

From time to time, we enter into business relationships, including joint ventures and collaborative arrangements, for the R&D, manufacture and/or commercialization of products and/or product candidates. In addition, we acquire product and R&D technology rights and establish R&D collaborations with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. These arrangements generally provide for nonrefundable, upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. The activities under these collaboration agreements are performed with no guarantee of either technological or commercial success, and each is unique in nature.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require counterparties to execute confidentiality agreements upon commencement of a business relationship with us. However, others could either develop independently the same or similar information or unlawfully obtain access to our information.

Kirin-Amgen, Inc.

During the first quarter of 2018, we acquired the remaining 50% ownership interest of Kirin-Amgen, Inc. (K-A), from Kirin Holdings Company, Limited (Kirin), making K-A a wholly owned subsidiary of Amgen. Prior to the closing of the share acquisition, K-A was a 50-50 joint venture with Kirin. K-A develops and then licenses all product rights that have been transferred from Amgen and Kirin. See Part IV—Note 3, Business combinations and Note 10, Related party transactions, to the Consolidated Financial Statements.

Prior to the closing of the share acquisition, K-A had given us exclusive licenses to manufacture and market (i) filgrastim and pegfilgrastim in the United States; Europe; Canada; Australia; New Zealand; all Central American, South American, Middle Eastern and African countries; and certain countries in Asia; (ii) darbepoetin alfa and romiplostim in the United States; Europe; Canada; Australia; New Zealand; Mexico; all Central and South American countries and certain countries in Central Asia, Africa and the Middle East; and (iii) recombinant human erythropoietin in the United States. We currently market pegfilgrastim, filgrastim, darbepoetin alfa, recombinant human erythropoietin and romiplostim under the brand names Neulasta®, NEUPOGEN®/GRANULOKINE®, Aranesp®, EPOGEN® and Nplate®, respectively. Under these agreements, Amgen paid K-A royalties based on product sales. In addition, Amgen received payments from K-A for milestones earned and for conducting certain R&D activities on K-A's behalf.

K-A has also given and continues to grant Kirin exclusive licenses to manufacture and market (i) filgrastim and pegfilgrastim in Japan, Taiwan and South Korea; (ii) darbepoetin alfa, romiplostim and brodalumab in Japan, China, Taiwan, South Korea and certain other countries and/or regions in Asia; and (iii) recombinant human erythropoietin in Japan. K-A also gave Kirin and Amgen co-exclusive licenses to manufacture and market filgrastim, pegfilgrastim and recombinant human erythropoietin in China, which Amgen subsequently assigned to Kirin, and as a result, Kirin now manufactures and markets filgrastim and recombinant human erythropoietin exclusively in China. Kirin markets filgrastim, pegfilgrastim, darbepoetin alfa, romiplostim, recombinant human erythropoietin and brodalumab under the brand names GRAN®/Grasin®, Peglasta®/Neulasta®/G-Lasta®, NESP®/Aranesp®, ROMIPLATE®, ESPO® and LUMICEF®, respectively. Under these agreements, Kirin pays K-A royalties based on product sales. In addition, Kirin

receives payments from K-A for conducting certain R&D activities on K-A's behalf.

Novartis

In April 2017, we expanded our existing migraine collaboration with Novartis. In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig®. Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig® and other specified migraine programs. Novartis pays Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide.

UCB

We are in a collaboration with UCB for the development and commercialization of EVENITY™. Under our collaboration, UCB has the rights to lead commercialization for EVENITY™ for all indications in Europe, China (excluding Hong Kong) and Brazil. All other territories have been allocated to Amgen. Generally, development costs and future worldwide commercialization profits and losses related to the collaboration after accounting for expenses are shared equally.

Bayer HealthCare Pharmaceuticals Inc.

We are in a collaboration with Bayer HealthCare Pharmaceuticals Inc. (Bayer) to jointly develop and commercialize Nexavar® (sorafenib). In 2015, we amended the terms of our collaboration agreement with Bayer, which terminated the co-promotion agreement in the United States and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits in the United States. In lieu of this profit share, Bayer now pays us a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Outside the United States and Japan, Bayer manages all commercialization activities and incurs all sales and marketing expenditures and mutually agreed R&D expenses, and we reimburse Bayer for half of those expenditures. In all countries outside the United States and Japan, we receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs. The rights to develop and market Nexavar® in Japan are reserved to Bayer.

DaVita Inc.

In January 2017, we entered into a six-year supply agreement with DaVita Inc. (DaVita), which superseded the previously existing seven-year supply agreement that commenced in 2012. Pursuant to the 2017 agreement, we supply EPOGEN® and Aranesp® in amounts necessary to meet specified annual percentages of DaVita's and its affiliates' requirements for erythropoiesis-stimulating agents (ESAs) used in providing dialysis services in the United States and Puerto Rico. Such percentage varies during the term of the agreement, but in each year is at least 90%. The agreement expires in 2022. The agreement may be terminated by either party before expiration of its term in the event of certain breaches of the agreement by the other party.

Human Resources

As of December 31, 2018, Amgen had approximately 21,500 staff members. We consider our staff relations to be good.

Executive Officers of the Registrant

Mr. Robert A. Bradway, age 56, has served as a director of the Company since 2011 and Chairman of the Board of Directors since 2013. Mr. Bradway has been the Company's President since 2010 and Chief Executive Officer since 2012. From 2010 to 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy, and served as Executive Vice President and Chief Financial Officer from 2007 to 2010. Prior to joining the Company, he was a Managing Director at Morgan Stanley in London, where, beginning in 2001, he had responsibility for the firm's banking department and corporate finance activities in Europe. Mr. Bradway has been a director of The Boeing Company, an aerospace company and manufacturer of commercial airplanes, defense, space and securities systems, since 2016. He has served on the board of trustees of the University of Southern California since 2014 and on the advisory board of the Leonard D. Schaeffer Center for Health Policy and Economics at that university since 2012. From 2011 to 2017, Mr. Bradway was a director of Norfolk Southern Corporation, a transportation company.

Mr. Murdo Gordon, age 52, became Executive Vice President, Global Commercial Operations in 2018. Prior to joining the Company, Mr. Gordon was the Chief Commercial Officer at Bristol-Myers Squibb Company (BMS) from 2016 to July 2018. Mr. Gordon served as Head of Worldwide Markets at BMS from 2015 to 2016. Prior to this, Mr. Gordon served in a variety of leadership roles at BMS for over 25 years.

Mr. Jonathan P. Graham, age 58, became Senior Vice President, General Counsel and Secretary in 2015. From 2006 to 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From 2004 to 2006, Mr. Graham was Vice President, Litigation and Legal Policy, at General Electric Company (GE). Prior to GE, Mr. Graham was a partner at Williams & Connolly LLP.

Ms. Lori A. Johnston, age 54, became Senior Vice President, Human Resources in 2016. From 2012 to 2016, Ms. Johnston was Executive Vice President and Chief Administrative Officer of Celanese Corporation. From 2006 to 2012, Ms. Johnston served in a series of progressive leadership roles at the Company, with her last position being Vice President, Human Resources. Prior to joining the Company, Ms. Johnston held human resources and other positions at Dell Inc.

Mr. David W. Meline, age 61, became Executive Vice President and Chief Financial Officer in 2014. From 2011 to 2014, Mr. Meline served as Senior Vice President and Chief Financial Officer at 3M Company (3M). From 2008 to 2011, Mr. Meline served as Vice President, Corporate Controller and Chief Accounting Officer of 3M. Prior to 2008, Mr. Meline served in a variety of senior leadership roles at General Motors Company for over 20 years, with his last position being Vice President and Chief Financial Officer, North America. Mr. Meline has been a director of ABB Ltd., a global industrial technology company based in Switzerland, since 2016, currently serving as the chairman of the Finance, Audit and Compliance Committee. Mr. Meline was a director of TRW Automotive Holdings, Corp., a supplier of automotive systems, modules and components, from 2014 until its acquisition by ZF Friedrichshafen AG in 2015.

Ms. Cynthia M. Patton, age 57, became Senior Vice President and Chief Compliance Officer in 2012. Ms. Patton joined the Company in 2005. From 2005 to 2010, Ms. Patton was Associate General Counsel. From 2010 to 2012, Ms. Patton was Vice President, Law. Previously, Ms. Patton served as Senior Vice President, General Counsel and Secretary of SCAN Health Plan from 1999 to 2005.

Mr. David A. Piacquad, age 62, became Senior Vice President, Business Development, in 2014. Mr. Piacquad joined the Company in 2010 and served as Vice President, Strategy and Corporate Development, until 2014. Mr. Piacquad served as Vice President, Business Development in 2014. Prior to joining the Company, from 2009 to 2010 Mr. Piacquad was Principal of David A. Piacquad Consulting LLC. From 2006 to 2009, Mr. Piacquad served as Senior Vice President, Business Development and Licensing at Schering-Plough Corporation (Schering-Plough). Prior to Schering-Plough, Mr. Piacquad served in a series of leadership roles in finance and business development at J&J, with his last position being Vice President, Ventures and Business Development.

Dr. David M. Reese, age 56, became Executive Vice President, Research and Development in 2018. Dr. Reese joined the Company in 2005 and has held leadership roles in development, medical sciences and discovery research. Dr. Reese was Senior Vice President, Translational Sciences and Oncology, from 2017 to 2018 and Senior Vice President, Translational Sciences, from 2015 to 2017. Prior to joining Amgen, Dr. Reese was director of Clinical Research for

the Breast Cancer International Research Group from 2001 to 2003 and a co-founder, president and chief medical officer of Translational Oncology Research International, a not-for-profit academic clinical research organization from 2003 to 2005. Dr. Reese previously served on the faculty at University of California, Los Angeles and the University of California, San Francisco.

Mr. Esteban Santos, age 51, became Executive Vice President, Operations, in 2016. Mr. Santos joined the Company in 2007 as Executive Director, Manufacturing Technologies. From 2008 to 2013, Mr. Santos held a number of Vice President roles at the Company in engineering, manufacturing, site operations and drug product. From 2013 to 2016, Mr. Santos was Senior Vice President, Manufacturing. Prior to joining the Company, Mr. Santos served as Site General Manager of J&J's Cordis operation in Puerto Rico. Prior to J&J, Mr. Santos held several management positions in GE's industrial and transportation businesses.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Part IV—Note 4, Revenues and Note 13, Property, plant and equipment, to the Consolidated Financial Statements.

Investor Information

Financial and other information about us is available on our website at www.amgen.com. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission (SEC). In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected, without charge, at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.)

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability.

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue initiatives to contain costs and manage drug utilization. These payers are increasingly focused on the effectiveness, benefits and costs of similar treatments, which could result for our products in lower reimbursement rates or narrower populations for whom payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, may limit our ability to set or adjust the price of our products based on their value, which could have a material adverse effect on our business. In the United States, the public discussions of drug pricing issues are likely to continue.

—Changing federal coverage and reimbursement policies and practices have impacted and may continue to impact access to and sales of our products

A substantial portion of our U.S. business relies on reimbursement from U.S. federal government healthcare programs and commercial insurance plans regulated by the U.S. federal and state governments. See Item 1. Business—Reimbursement. Our business has and will continue to be impacted by legislative actions changing U.S. federal reimbursement policy. For example, in February 2018, the U.S. Congress passed legislation requiring biopharmaceutical manufacturers to provide greater discounts beginning in 2019 on products dispensed to patients in the coverage gap between the initial coverage limit of Medicare Part D and the program's catastrophic-coverage threshold, which will reduce our net product sales relating to such patients. Additional legislative proposals have been introduced by members of Congress to overhaul provisions of the Patient Protection and ACA, to allow commercial-level re-importation of prescription medications from Canada or other countries and to enable Medicare to negotiate drug prices with biopharmaceutical manufacturers. Congressional focus on drug pricing has increased since the Democrats took control of the U.S. House of Representatives in November 2018. For example, in January 2019, the chair of the House Oversight and Reform Committee sent letters to twelve different biopharmaceutical manufacturers, including Amgen, seeking documents and detailed information about such companies' drug pricing. Both that committee and the Senate Finance Committee held committee hearings in January 2019 on the topic of drug pricing and have indicated that further committee hearings on the topic are likely.

Also our business has been and is expected to continue to be impacted by changes in U.S. federal reimbursement policy resulting from executive actions, federal regulations, or federal demonstration projects. For example, in May 2018, the U.S. presidential administration released a drug pricing “blueprint” and requested public comment on an array of policy ideas intended to increase competition, improve the negotiating power of the federal government, reduce drug prices and lower patient out-of-pocket costs. This blueprint includes a number of policy ideas with the potential to significantly impact, whether individually or collectively, our industry. Such proposals include moving coverage and reimbursement for Medicare Part B drugs into Medicare

Part D, instituting a competitive acquisition program for Part B drugs in which competing third-party vendors take on the financial risk of acquiring drugs and billing Medicare, removing the safe harbor protection under the federal anti-kickback statute for drug rebates paid to payers, and requiring the inclusion of drug price information in direct-to-consumer drug advertising.

Since that time, the president and/or federal agencies, such as CMS, have announced a number of demonstration projects, recommendations and proposals to implement various elements described in the drug pricing blueprint. CMS, the federal agency responsible for administering Medicare and overseeing state Medicaid programs and Health Insurance Marketplaces, has substantial power to implement policy changes or demonstration projects that can quickly and significantly affect how drugs, including our products, are covered and reimbursed. For example, in October 2018, President Trump announced that CMS was evaluating a pilot program proposed to initially cover fifty percent of spending on Part B single-source drugs referred to as the "International Price Index" that would, among other things, set the Medicare payment amount for such single-source drugs to more closely align with international drug prices. CMS has taken additional actions to implement other elements described in the administration's drug-pricing blueprint, including issuing guidance to allow certain Medicare plans offered by private insurance companies to require that patients receiving Medicare Part B drugs first try a drug preferred by the plan before such plan will cover another therapy and proposing lower reimbursement rates for new Part B drugs. And on January 31, 2019, the U.S. Department of Health and Human Services released a proposal to revise the federal anti-kickback statute safe harbor regulations to exclude from safe harbor protection certain rebates and other forms of remuneration paid by a manufacturer of prescription drugs to Medicaid managed care organizations or plan sponsors under Medicare Part D, either directly or through PBMs.

Further, CMS has undertaken demonstration projects to test care models, such as the CMS Oncology Care Model, which provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively impacting the efficacy of care. We believe the Oncology Care Model has reduced utilization of certain of our oncology products by participating physician practices and may continue to do so in the future. In addition, CMS has solicited suggestions regarding other potential care models.

In this dynamic environment, we are unable to predict which or how many of these various federal policy, legislative or regulatory changes may ultimately be enacted, to the extent that these or other federal government initiatives decrease or modify the coverage or reimbursement available for our products, limit our ability to offer co-pay payment assistance to commercial patients, require that we pay increased rebates or shift other costs to us, limit or impact our decisions regarding the pricing of biopharmaceutical products or otherwise reduce the use of our U.S. products, such actions could have a material adverse effect on our business and results of operations.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. Government price reporting regulations are complex and may require a manufacturer to update certain previously submitted data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts.

—Changing state reimbursement and pricing actions may impact access to and have impacted and may continue to impact sales of our products

At the state level, government actions or ballot initiatives can also affect how our products are covered and reimbursed and/or create additional pressure on our pricing decisions. A number of states have adopted, and many other states have discussed and debated and are considering, new pricing actions, including proposals designed to require biopharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling or cap on biopharmaceutical products. Existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be impacting industry pricing decisions. For example, in October 2017, California enacted a drug-pricing transparency bill that requires biopharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Other states are seeking to change the way their states pay for drugs for patients covered by state programs. For example, in August 2018 the Ohio Department of Medicaid ordered that all the state's Medicaid

managed care plans terminate and renegotiate contracts with PBMs to eliminate the drug purchasing model in which PBMs bill the state more than they reimburse pharmacists for filling Medicaid patient prescriptions. In January 2019, California's governor issued an executive order expanding state Medicaid coverage and directing state agencies and programs to consolidate drug purchases and to negotiate drug prices with manufacturers. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce their costs. Ultimately, as with U.S. federal government actions, existing or future state government actions or ballot initiatives may also have a material adverse effect on our product sales, business and results of operations.

—U.S. commercial payer actions have impacted and may continue to impact access to and sales of our products
Payers, including healthcare insurers, PBMs and group purchasing organizations, increasingly seek ways to reduce their and their respective members' costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater portion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and limitations on patients' use of manufacturer commercial co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs). Payers have sought and will likely continue to seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage, particularly in treatment areas where the payer has taken the position that multiple branded products are therapeutically comparable. Payers also control costs by imposing restrictions on access to or usage of our products, such as requiring that patients first try a drug preferred by the payer or receive the payer's prior authorization before covering the product, or that patients use a mail-order pharmacy or mail-order pharmacy or a limited network of fully-owned specialty pharmacies; payers may also choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, the burdensome administrative processes required for physicians to demonstrate or document that the patients for whom Repatha® has been prescribed meet payer utilization management criteria has limited and may continue to limit patient access to Repatha® treatment. In an effort to reduce barriers to access, we reduced the net price of Repatha® by providing greater discounts and rebates to payers, including PBMs that administer Medicare Part D prescription drug plans. However, affordability of patient out-of-pocket co-pay cost has and may continue to limit patient use. For example, a very high percentage of Medicare patients have abandoned their Repatha® prescriptions rather than pay their co-pay payment. In late 2018 and early 2019, we introduced a set of new NDCs to make Repatha® available at a lower list price to attempt to address affordability for patients, particularly those on Medicare. Despite the recent net and list price reductions, payers may continue to restrict patient access, change formulary coverage for Repatha®, seek further discounts or rebates or take other actions that could reduce our sales of Repatha®. Further, our introduction of the new NDCs may not be rapidly adopted by payers, which could continue to limit patient use and could also reduce our sales of Repatha®.
Significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. For example, in the United States, the top three PBMs now oversee greater than two-thirds of prescription claims as well as government and commercial covered lives. The consolidation among insurers, PBMs and other payers, including through integrated delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other drug manufacturers and has resulted in greater price discounts, rebates and fees for other services being realized by those payers. For example, during the fourth quarter of 2018, two of the nation's largest PBMs, Express Scripts and CVS Health, completed their combinations with major insurance companies Cigna and Aetna, respectively. Additional consolidation would further increase the leverage of such entities. Ultimately, additional discounts, rebates, coverage or plan changes, restrictions or exclusions imposed by these commercial payers could have a material adverse effect on our product sales, business and results of operations.
—Government and commercial payer actions outside the United States have impacted and will continue to impact access to and sales of our products
Outside the United States, we expect countries will continue to take actions to reduce their drug expenditures. See Item 1. Business—Reimbursement. International reference pricing (IRP) has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. IRP policies can quickly and frequently change and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or that it does not meet certain cost effectiveness thresholds. For example, despite the EMA's May 2018 approval of Repatha® for the treatment of patients with established atherosclerotic disease, reimbursement for Repatha® in France and Germany has remained limited to narrower patient populations (such as those with homozygous familial hypercholesterolemia)

following national health technology assessments in mid-2018. While the pricing and reimbursement process in those countries remains ongoing, these assessments currently limit our efforts in France and Germany to expand Repatha® access to the broader patient population covered by the approved label. Failure to obtain coverage and reimbursement for our products, a deterioration in their existing coverage and reimbursement, or a decline in the timeliness or certainty of payment by payers to physicians and other providers could negatively impact the ability or willingness of healthcare providers to prescribe our products for their patients or could otherwise negatively affect the use of our products or the prices we receive for them. Such changes could have a material adverse effect on our product sales, business and results of operations.

We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future.

We currently face competition from biosimilars in both Europe and the United States, and we expect to face increasing biosimilar and/or generics competition this year and beyond. Expiration or successful challenge of applicable patent rights or

expiration of an applicable exclusivity period would accelerate such competition, and we expect to face more litigation regarding the validity and/or scope of our patents. Our products may also experience greater competition from lower-cost biosimilars or generics that come to market when branded products that compete with our products lose their own patent protection. To the extent that governments adopt more permissive approval frameworks and competitors are able to obtain broader or expedited marketing approval for biosimilars and generics, the rate of increased competition for our products could accelerate.

In the EU, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries have adopted and others are attempting to adopt biosimilar uptake measures such as requiring physician prescribing quotas or promoting switching or pharmacy substitution of biosimilars for the corresponding reference products, and other countries may adopt similar measures. Some EU countries impose automatic price reductions upon market entry of one or more biosimilar competitors. While the degree of competitive impact of biosimilar competition differs between EU countries and between products, in the EU the overall use of biosimilars and the rate at which product sales of innovative products are being impacted by biosimilar competition is increasing.

In the United States, the ACA authorized the FDA to approve biosimilars via a separate, abbreviated pathway. See Item 1. Business—Government Regulation—Regulation in the United States—Approval of Biosimilars. The first biosimilar entrant into the U.S. market, Sandoz's Zarxio®, is a biosimilar version of NEUPOGEN® and was launched in the United States in 2015. Since then, the FDA has approved additional biosimilars, including biosimilar versions of ENBREL, Neulasta® and EPOGEN®, and a growing number of companies have announced that they are also developing biosimilar versions of our products. Two biosimilar versions of Neulasta® are now marketed in the United States and others may receive approval in 2019. Impact to our Neulasta® sales could accelerate as additional competitors are launched. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. The approved biosimilar version of EPOGEN® has also launched in the United States, and we are currently involved in patent litigation with the manufacturer of the approved version of ENBREL. Manufacturers of biosimilars may attempt to compete with our products by offering lower list prices, greater discounts or rebates, or contracts that offer longer-term pricing or a broader portfolio of other products. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For information related to our biosimilars and generics patent litigation, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. See Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in present and future intellectual property litigation. The U.S. pathway includes the option for biosimilar products that meet certain criteria to be approved as interchangeable with their reference products. Some companies currently developing or already marketing biosimilars may seek to register their products as interchangeable biosimilars, which could make it easier for pharmacists to substitute those biosimilars for our reference products or could encourage prescribers or payers who are inclined to select the interchangeable biosimilar over our innovative products or our biosimilars. In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity. For example, the FDA is considering whether subsequent changes to a licensed biologic would be protected by the remainder of the reference product's original 12-year exclusivity period (a concept known in the generic drug context as "umbrella exclusivity"). If the FDA were to decide that umbrella exclusivity does not apply to biological reference products or were to make other changes to the exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, public, legislative, and FDA efforts to promote price competition through policies enabling easier generic and biosimilar entry, including efforts to lower standards for demonstrating biosimilarity or interchangeability and provide greater clarity for how to do so, and through changes to the reimbursement policies for biologics.

Upon the expiration or loss of patent protection for one of our small-molecule products, we can lose the majority of revenues for that product in a very short period of time. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. Our U.S. composition of matter patent for Sensipar®, a small-molecule product, expired in March 2018. We are engaged in litigation with a number of companies seeking to market generic versions

of Sensipar® surrounding our U.S. formulation patent that expires in September 2026. Several of these generic versions of Sensipar® have been approved by the FDA, and the manufacturer of one of the approved generic versions began selling its product in late 2018 before reaching a settlement agreement with us in early January 2019. We were subsequently sued by a manufacturer of another approved generic version of Sensipar® who is contending that provisions of its own settlement agreement with Amgen have been triggered by the first manufacturer's at-risk launch, giving this second manufacturer a right to market its own generic version under its settlement agreement. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. While no generic versions of Sensipar® are currently available for sale, one or more other companies may elect to launch their approved generic versions at-risk prior to the conclusion of our ongoing litigation, or may seek and obtain a judicial declaration that they are permitted to launch their generic versions. If this happens, our product sales for Sensipar® could be materially and adversely affected.

While we are unable to predict the precise impact of biosimilars and generics on our products, we are currently facing and expect to face greater competition in the United States, Europe and elsewhere this year and beyond as a result of biosimilar and

generic competition and downward pressure on our product prices and sales. This competition has had and could increasingly have a material adverse effect on our product sales, business and results of operations.

Our products face substantial competition.

We operate in a highly competitive environment. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition. We expect that our products will compete with new drugs currently in development, drugs currently approved for other indications that may later be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical companies and generics manufacturers of pharmaceutical products are expanding into the biotechnology field, and some pharmaceutical companies and generics manufacturers have formed partnerships to pursue biosimilars. In addition, some of our competitors may have technical, competitive or other advantages over us for the development of technologies and processes or greater experience in particular therapeutic areas, and consolidation among pharmaceutical and biotechnology companies can enhance such advantages. These advantages may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products or new product indications they may bring to market. As a result, our products may compete against products that offer higher rebates or discounts, lower prices, equivalent or superior performance, better safety profiles, easier administration, earlier market availability or other competitive features. If we are unable to compete effectively, this could reduce sales, which could have a material adverse effect on our business and results of operations.

Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in present and future intellectual property litigation.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Driven by cost pressures, efforts to limit or weaken patent protection for our industry are increasing. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges to patents may come from potential competitors or from parties other than those who seek to market a potentially-infringing product. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, and are currently and expect to be in the future, involved in patent litigation. These matters have included and may in the future include litigation with manufacturers of products that purport to be biosimilars of certain of our products for patent infringement and for failure to comply with certain provisions of the Biologics Price Competition and Innovation Act. A determination made by a court, agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed, or made the subject of reconsideration through further proceedings. A patent dispute or litigation may not discourage a potential violator from bringing the allegedly-infringing product to market prior to a final resolution of the dispute or litigation. The period from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We may be subject to competition during this period and may not be able to recover fully from the losses, damages, and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch-Waxman Act, our products approved by the FDA under the FDCA may be the subject of patent litigation with generics competitors before expiry of the five-year period of data exclusivity provided for under

the Hatch-Waxman Act and prior to the expiration of the patents listed for the product. Likewise, our innovative biologic products may be the subject of patent litigation prior to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the 12-year exclusivity period provided under the ACA. In addition, we are facing patent litigation involving claims that the biosimilar product candidates we are working to develop infringe the patents of other companies that manufacture, market or sell the applicable reference products. For example, we are currently engaged in litigation in the United States regarding MVASI™, KANJINTI™ and AMJEVITA™, and in Europe we are engaged in litigation regarding AMGEVITA™. While we may attempt to challenge the patents held by the companies manufacturing, marketing or selling the applicable reference products, our efforts may be unsuccessful. Alternatively, such patents may contribute to a decision by us to not pursue all of the same labeled indications as are held by these companies. For information related to our patent litigation, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

Certain of the existing patents on our products have expired. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents. As our patents expire, competitors are able to legally produce and market similar products or technologies, including biosimilars, which may have a material adverse effect on our product sales, business and results of operations. In addition, competitors may be able to invalidate, design around or otherwise circumvent our patents and sell competing products.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. Professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies. In addition, a growing number of organizations are providing assessments of the value and pricing of biopharmaceutical products, and even organizations whose guidelines have historically been focused on clinical matters have begun to incorporate analyses of the cost effectiveness of various treatments into their treatment guidelines and recommendations. Value assessments may come from private organizations that publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. Some companies and payers have announced pricing and payment decisions based in part on the assessments of private organizations. For example, CVS Caremark indicated in August 2018 that it will begin utilizing third-party cost effectiveness analyses to make formulary and coverage determinations for newly-approved drugs. In addition, government health technology assessment organizations in many countries make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service impact of new, emerging and existing medicines and treatments. Such health technology assessment organizations may recommend reimbursement for our product for a narrower indication than was approved by applicable regulatory agencies or may recommend against reimbursement entirely. Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

Our current products and products in development cannot be sold without regulatory approval.

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in foreign countries to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and foreign regulatory agencies have substantial authority to require additional testing and reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The sanctions could include the FDA's or foreign regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions. Obtaining and maintaining regulatory approvals have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations, or change their interpretations of laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to laws or regulations governing manufacturer communications concerning drug products and drug product candidates, and whether such changes could have a material adverse effect on our product sales, business and results of operations. In the United States, a partial federal government shutdown halted the work of many federal agencies and their employees from late December 2018

through late January 2019. While federal employees have since returned to work, a subsequent extended shutdown could result in reductions or delays of FDA's activities, including with respect to our ongoing clinical programs, our manufacturing of our products and product candidates, and our product approvals.

Regulatory authorities may also question the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical endpoint. For example, a therapeutic oncology product candidate may be evaluated for its ability to extend the length of time during and after the treatment that a patient lives without the disease worsening, measured by progression-free survival (PFS). Demonstrating that the product candidate produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival, or the time that the patients remain alive. In the cardiovascular setting, a heart disease therapeutic

candidate may be evaluated for its ability to reduce LDL-C levels, as elevated LDL-C level has been a surrogate endpoint for cardiovascular events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, our initial FDA application for Repatha® sought approval for a broader patient population based on data demonstrating that Repatha® reduced LDL-C levels. However, the FDA initially approved Repatha® in 2015 only for a subset of those patients, citing among other things the absence of positive outcomes data showing that Repatha® prevents cardiovascular events. In December 2017, the FDA granted broader approval of Repatha® to reduce the risk of certain cardiovascular events, and also to be used, alone or in combination with other lipid-lowering therapies, for the treatment of adults with primary hyperlipidemia to reduce LDL-C, only after our large phase 3 outcomes study evaluating the ability of Repatha® to prevent cardiovascular events met its primary composite endpoint and key secondary composite endpoint. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion or at all may delay our clinical development and regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current labels.

Some of our products have been approved by U.S. and foreign regulatory authorities on an accelerated or conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, in March 2018, we announced that the FDA approved BLINCYTO® under accelerated approval for the treatment of adults and children with B-cell precursor ALL in first or second complete remission with minimal residual disease greater than or equal to 0.1 percent. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators re-evaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications or even withdraw the product from the market.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required to continuously collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In the United States, for our products with approved REMS (see Item 1. Business—Government Regulation—Post-approval Phase), we are required to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to ensure that a drug's benefits outweigh the risks, and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety and malfunctions. If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed products can also be affected by safety problems or signals occurring with respect to products that are similar to ours or that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis involves the use of various statistical methods to combine

results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that may result in our decision not to commercialize a product candidate;
- requirement of risk management activities or other regulatory agency compliance actions related to the promotion and sale of our products;
- mandated post-marketing commitments or pharmacovigilance programs for our approved products;
- product recalls of our approved products;

- required changes to the processes used in the manufacture of our products, which could increase our manufacturing costs and affect the availability of contract manufacturers we may utilize to assist in such manufacturing;
- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;
- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or
- fewer treatments or product candidates being approved by regulatory bodies.

For example, the FDA is currently evaluating our BLA for EVENITY™ for the treatment of postmenopausal women with osteoporosis at high risk of fracture. In January 2018, the FDA's BRUDAC recommended that the FDA approve EVENITY™, but also suggested that the FDA require appropriate post-marketing review to evaluate a potential cardiovascular risk seen in one of the EVENITY™ pivotal clinical trials. See Item 1. Business—Significant Developments. While the FDA is not bound to follow the recommendations of its advisory committees, it often does; if the FDA approves EVENITY™ it may require that we complete a post-marketing study, which could be time consuming and costly.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets, there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the ACA provided for such a pathway; while the FDA continues to implement it, discussions continue as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products. See We currently face competition from biosimilars and expect to face increasing competition from biosimilars and generics in the future. Delays or uncertainties in the development or implementation of such pathways could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area. Further, we cannot predict whether any repeal or reform of the ACA would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars or on our marketed biosimilars. In addition, if we are unable to bring our biosimilar products to market on a timely basis, and secure "first-to-market" or other advantageous positions, our future biosimilar sales and results of operations could be materially and adversely affected.

We may not be able to develop commercial products despite significant investments in R&D.

Amgen invests heavily in R&D. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects produce commercial products. Product candidates, including biosimilar product candidates, or new indications for existing products (collectively, product candidates) that appear promising in the early phases of development may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results, for reasons that could include changes in the standard of care of medicine;
- the product candidate was not effective or not more effective than currently available therapies in treating a specified condition or illness;
- the product candidate was not cost effective in light of existing therapeutics;
- the product candidate had harmful side effects in animals or humans;
- the necessary regulatory bodies, such as the FDA or EMA, did not approve the product candidate for an intended use;
- the product candidate was not economical for us to manufacture and commercialize;
- other parties had or may have had proprietary rights relating to our product candidate, such as patent rights, and did not let us sell it on reasonable terms, or at all;
- we and certain of our licensees, partners, contracted organizations or independent investigators may have failed to effectively conduct clinical development or clinical manufacturing activities;
- the pathway to regulatory approval or reimbursement for product candidates was uncertain or not well-defined; and
- the biosimilar product candidate failed to demonstrate the requisite biosimilarity to the applicable reference product, or was otherwise determined by a regulatory authority to not meet applicable standards for approval.

We have spent considerable time, energy and resources developing our expertise in human genetics with the belief that genetics could meaningfully aid our search for new medicines and help guide our research and development decisions and investments. We have focused our R&D strategy on drug targets validated by genetic or other

compelling human evidence. However,

product candidates based on genetically validated targets remain subject to the uncertainties of the drug development process and may not reach the market for a number of reasons, including the factors listed above.

A number of our product candidates have failed or been discontinued at various stages in the product development process. For example, in May 2015, we terminated our participation in the co-development and commercialization of brodalumab with AstraZeneca. The decision was based on events of suicidal ideation and behavior in the brodalumab program, which we believed likely would necessitate restrictive labeling that would limit the appropriate patient population. Inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product for any of the reasons discussed could potentially have a negative impact on our product sales and earnings and could result in a significant impairment of in-process research and development (IPR&D) or other intangible assets.

We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.

Before we sell any products, we must conduct clinical trials to demonstrate that our product candidates are safe and effective for use in humans. The results of those clinical trials are used as the basis to obtain approval from regulatory authorities such as the FDA and EMA. See Our current products and products in development cannot be sold without regulatory approval. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims. The length of time, number of trial sites and number of patients required for clinical trials vary substantially, and we may spend several years and incur substantial expense in completing certain clinical trials. In addition, we may have difficulty finding a sufficient number of clinical trial sites and patients to participate in our clinical trials, particularly if competitors are conducting clinical trials in similar patient populations. Patients may withdraw from clinical trials at any time, and privacy laws and/or other restrictions in certain countries may restrict the ability of clinical trial investigators to conduct further follow-up on such patients, which may adversely affect the interpretation of study results. Delays and complications in planned clinical trials can result in increased development costs, associated delays in regulatory approvals and in product candidates reaching the market and revisions to existing product labels.

Further, to increase the number of patients available for enrollment in our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of locations where our experience conducting clinical trials is more limited, including Russia, India, China, South Korea, the Philippines, Singapore and some Central and South American countries, either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to understand the unique regulatory environments of individual countries. Further, we must ensure the timely production, distribution and delivery of the clinical supply of our product candidates to numerous and varied clinical trial sites. If we fail to adequately manage the design, execution and diverse regulatory aspects of our large and complex clinical trials or to manage the production or distribution of our clinical supply, corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our products or product candidates or to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations could be materially and adversely affected.

We rely on independent third-party clinical investigators to recruit patients and conduct clinical trials on our behalf in accordance with applicable study protocols, laws and regulations. Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. In some circumstances, we enter into co-development arrangements with other pharmaceutical and medical devices companies that provide for the other company to conduct certain clinical trials for the product we are co-developing or to develop a diagnostic test used in screening patients for our clinical trials. See Some of our pharmaceutical pipeline and of our commercial product sales relies on collaborations with third parties, which may adversely affect the development and sale of our products. We also may acquire companies that have past or ongoing clinical trials or rights to products or product candidates for which clinical trials have been or are being conducted. These trials may not have been conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of these trials, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If

regulatory authorities determine that we or others, including our licensees or co-development partners, or the independent investigators or vendors selected by us, our co-development partners or by a company we have acquired or from which we have acquired rights to a product or product candidate, have not complied with regulations applicable to the clinical trials, those authorities may refuse or reject some or all of the clinical trial data or take other actions that could delay or otherwise negatively impact our ability to obtain or maintain marketing approval of the product or indication. In addition, delays or failures to develop diagnostic tests for our clinical trials can affect the timely enrollment of such trials and lead to delays or inability to obtain marketing approval. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

In addition, some of our clinical trials utilize drugs manufactured and marketed by other pharmaceutical companies. These drugs may be administered in clinical trials in combination with one of our products or product candidates or in a head-to-head

study comparing the products' or product candidates' relative efficacy and safety. In the event that any of these vendors or pharmaceutical companies have unforeseen issues that negatively impact the quality of their work product or create a shortage of supply, or if we are otherwise unable to obtain an adequate supply of these other drugs, our ability to complete our applicable clinical trials and/or evaluate clinical results may also be negatively impacted. As a result, such quality or supply problems could adversely affect our ability to timely file for, gain or maintain regulatory approvals worldwide.

Clinical trials must be designed based on the current standard of medical care. However, in certain diseases, such as cancer, the standard of care is evolving rapidly. In such diseases, the duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on standards of medical care that are no longer the current standards by the time such trials are completed, limiting the utility and application of such trials.

We may not obtain favorable clinical trial results and therefore may not be able to obtain regulatory approval for new product candidates or new indications for existing products and/or maintain our current product labels. Participants in clinical trials of our products and product candidates may also suffer adverse medical events or side effects that could, among other factors, delay or terminate clinical trial programs and/or require additional or longer trials to gain approval.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a risk management plan for our product or for approval of a new indication. For example, in connection with the June 2011 ESA label changes, we agreed to and conducted additional clinical trials examining the use of ESAs in CKD. Additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense and the outcomes could result in further label restrictions or the loss of regulatory approval for an approved indication, each of which could have a material adverse effect on our product sales, business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our products, our business and results of operations.

Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.

Many of our products and product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. For example, Neulasta® is available as part of the Neulasta® Onpro® kit, and our AutoTouch® reusable auto-injector is used with Enbrel Mini® single-dose prefilled cartridges. In addition, some of our products or product candidates may also require the use of a companion diagnostic device such as a device that determines whether the patient is eligible to use our drug or that helps ensure its safe and effective use. Our product candidates or expanded indications of our products used with such devices may not be approved or may be substantially delayed in receiving regulatory approval if development of such devices is delayed, such devices do not also gain or maintain regulatory approval or clearance, or if such devices do not remain commercially available. When approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may delay receipt of regulatory approval. In addition, some of these devices may be provided by single-source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or clearance by the applicable regulatory agencies. We are also dependent on those third-party companies continuing to meet applicable regulatory or other requirements. Failure to successfully develop, modify, or supply the devices, delays in or failures of the Amgen or third-party studies, or failure of us or the third-party companies to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs; delays in, or failure to obtain or maintain, regulatory approval; and/or associated delays in a product candidate reaching the market or in the addition of new indications for existing products. We are also required to collect and assess user complaints, adverse events, and malfunctions regarding our devices, and actual or perceived safety problems or concerns with a device used with our product can lead to regulatory actions and impacts to our products. See Our current products and products in development cannot be sold without regulatory approval. Additionally, regulatory agencies conduct routine monitoring and conduct inspections to identify and evaluate potential issues with our devices. For example, in 2017 the FDA reported on its adverse event reporting system that it is evaluating our Neulasta® Onpro® kit. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our

product from the market. Further, failure to successfully develop, supply, or gain or maintain approval for these devices could adversely affect sales of the related, approved products.

Some of our pharmaceutical pipeline and of our commercial product sales relies on collaborations with third parties, which may adversely affect the development and sale of our products.

We depend on alliances with other companies, including pharmaceutical and biotechnology companies, vendors and service providers, for the development of a portion of the products in our pharmaceutical pipeline and for the commercialization and sales of certain of our commercial products. For example, we have collaborations with third parties under which we share development rights, obligations and costs and/or commercial rights and obligations. See Item 1. Business—Business Relationships.

Failures by these parties to meet their contractual, regulatory, or other obligations to us, or any disruption in the relationships between us and these third parties, could have a material adverse effect on our pharmaceutical pipeline and business. In addition, our collaborative relationships for research and development and/or commercialization and sales often extend for many years and

may give rise to disputes regarding the relative rights, obligations and revenues of us and our collaboration partners, including the ownership or prosecution of intellectual property and associated rights and obligations. This could result in the loss of intellectual property rights or protection, delay the development and sale of potential pharmaceutical products, impact the effective sale and delivery of our commercialized products and lead to lengthy and expensive litigation, administrative proceedings or arbitration.

The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.

We are subject to income and other taxes in the United States and other jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for determining our provision for income tax.

Our tax returns are routinely examined by tax authorities in the United States and other jurisdictions in which we do business, and a number of audits are currently underway. Tax authorities, including the Internal Revenue Service (IRS), are becoming more aggressive in their audits and are particularly focused on the allocations of income and expense among tax jurisdictions. As previously disclosed, we received a Revenue Agent Report (RAR) from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Although final resolution of this complex matter is not likely within the next 12 months, such resolution could have a material negative impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities, and changes in applicable tax laws, regulations or administrative interpretations thereof. The 2017 Tax Act is complex and further regulations and interpretations are still being issued. We could face audit challenges on how we apply the new law that could have a negative impact on our provision for income taxes. A change to the U.S. tax system, such as a repeal or modification of the 2017 Tax Act, a change to the tax system in a jurisdiction where we have significant operations, such as the U.S. territory of Puerto Rico, or changes in tax law in the United States or other jurisdictions where we do business, could have a material and adverse effect on our business and on the results of our operations.

We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.

The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of our manufacturing facilities, in particular those in the U.S. territory of Puerto Rico and Thousand Oaks, California. See Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

We currently perform a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California. A substantial disruption in our ability to operate our Thousand Oaks, California manufacturing facility could materially and adversely affect our ability to supply our product candidates for use in our clinical trials, leading to delays in development of our product candidates.

In addition, we currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico. In late September 2017, Hurricane Maria made landfall on the island of Puerto Rico. The hurricane destroyed residential and commercial buildings, agriculture, communications networks and most of Puerto Rico's electric grid. While the critical manufacturing areas of our commercial manufacturing facility were not

significantly impacted by the storm, the restoration of electrical service on the island was a slow process, and our facility operated with electrical power from back-up diesel powered generators for some time. In January 2018, we reconnected to the Puerto Rico electric grid but have continued to use diesel generators as needed when sufficient electric power has not been reliably available. Further instability of the electric grid could require us to increase the use of our generators or even return to using them exclusively. In addition, future storms or other disasters or events could cause a more significant impact to our manufacturing operations. A substantial disruption in our ability to operate our Puerto Rico manufacturing facility (whether due to problems with the facility itself, the infrastructure and services available on the island, the unavailability of raw materials or supplies from vendors, the unavailability of key staff or otherwise) or get supplies and manufactured products transported to and from that location could materially and adversely affect

our ability to supply our products and affect our product sales. See Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

The impact of Hurricane Maria placed greater stress on the island's already challenged economy. Prior to Hurricane Maria, the government of Puerto Rico was unable to pay its roughly $72 billion in debt. In June 2016, the U.S. Congress passed the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA), which established a Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight through the development and approval of fiscal plans and budgets for Puerto Rico and to assist in its debt restructuring. In May 2017, after negotiations for debt restructuring with creditors were unsuccessful, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico and certain of its governmental entities, including the Puerto Rico Electric Power Authority (PREPA). Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code. The Governor of Puerto Rico declared a state of emergency and authorized a moratorium on the payment of general obligation bonds and other debts issued by certain instrumentalities, which moratorium has been extended and may continue to be extended while the Oversight Board is in effect. Given the severe conditions in Puerto Rico after Hurricane Maria, resolution of Puerto Rico's debt situation through the PROMESA judicial process has been delayed. In the case of PREPA, the effects of Hurricane Maria and several changes in PREPA's management have delayed reconstruction efforts.

In June 2018, the Oversight Board certified a budget for Puerto Rico's fiscal year 2019 that imposes significant expense reductions across the government. The Title III Court upheld government challenges to the budget, and the Governor and Legislature of Puerto Rico have now filed appeals before the U.S. Court of Appeals for the First Circuit. In addition, certain non-governmental entities have brought suit claiming the appointment process of the Oversight Board members set forth in PROMESA conflicts with the appointments clause of the U.S. Constitution. If the First Circuit were to hold that PROMESA has a constitutional infirmity and that actions taken by the Oversight Board are invalid, the commencement of all Title III proceedings could be invalid. In such event, the current debt restructuring process and the debtholder litigation stay under Title III of PROMESA could be in jeopardy.

In October 2018, the fiscal plan for Puerto Rico was updated, including a projected increase in federal disaster funding and projected material deficits once the stimulus effects of the disaster recovery dissipate. The fiscal plan stresses the importance of structural reforms to address Puerto Rico's challenging economic and demographic trends that may be difficult to implement as well as have a material adverse impact on our consolidated financial statements.

In addition, the 2017 Tax Act will no longer permit deferral of U.S. taxation on Puerto Rico earnings of U.S. companies (or their foreign subsidiaries), although these earnings generally will be taxed in the United States at a reduced 10.5% rate. Given Puerto Rico's challenged economy and hurricane recovery needs, it may be difficult for Puerto Rico to sustain or grow its manufacturing base due to competition from other foreign locations subject to a similar level of U.S. taxation, or U.S. locations due to the reduction in the U.S. corporate tax rate from 35% to 21%. The manufacturing sector contributes more than 45% of Puerto Rico's gross domestic product, and multinational companies with Puerto Rico operations contribute approximately 30% of Puerto Rico's revenue base.

While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, there is still a risk that Puerto Rico's ongoing economic challenges, the effects of Hurricane Maria and the potential impact of the 2017 Tax Act could negatively affect the territorial government's provision of utilities or other services in Puerto Rico that we use in the operation of our business, create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, or make it more expensive or difficult for us to operate in Puerto Rico, which could materially and adversely affect our ability to supply our products and affect our product sales.

We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We rely on unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the manufacturing of our commercial and clinical products. Certain of those raw materials, medical devices and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier. For example,

Insulet Corporation is our single-source of the on-body injector for our Neulasta® Onpro® kit. Also, certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin. Among the reasons we may be unable to obtain these raw materials, medical devices and components include:

- regulatory requirements or action by regulatory agencies or others;
- adverse financial or other strategic developments at or affecting the supplier, including bankruptcy;

- unexpected demand for or shortage of raw materials, medical devices or components;
- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall;
- a material shortage, contamination, recall and/or restrictions on the use of certain biologically derived substances or other raw materials;
- discovery of previously unknown or undetected imperfections in raw materials, medical devices or components; and
- labor disputes or shortages, including from the effects of health emergencies and natural disasters.

For example, in prior years we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility. Further quality issues that result in unexpected additional demand for certain components may lead to shortages of required raw materials or components (such as we have experienced with EPOGEN® glass vials). We may experience similar or other shortages in the future resulting in delayed shipments, supply constraints, clinical trial delays, contract disputes and/or stock-outs of our products. These or other similar events could negatively impact our ability to satisfy demand for our products or conduct clinical trials, which could have a material adverse effect on our product sales, business and results of operations.

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales. Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. We currently are involved in the manufacture of many of our products and plan to manufacture many of our product candidates. In addition, we currently use third-party contract manufacturers to produce, or assist in the production of, a number of our products, and we currently use contract manufacturers to produce, or assist in the production of, a number of our late-stage product candidates and drug delivery devices. See Item 1. Business—Manufacturing, Distribution and Raw Materials—Manufacturing. Our ability to adequately and timely manufacture and supply our products (and product candidates to support our clinical trials) is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which may be impacted by:

- capacity of manufacturing facilities;
- contamination by microorganisms or viruses, or foreign particles from the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies or natural disasters;
- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- updates of manufacturing specifications;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures;
- breakdown, failure, substandard performance or improper installation or operation of equipment; and/or
- delays in the ability of the FDA or foreign regulatory agencies to provide us necessary reviews, inspections and approvals, including as a result of a subsequent extended U.S. federal government shutdown.

If any of these or other problems affect production in one or more of our facilities or those of our third-party contract manufacturers, or if we do not accurately forecast demand for our products or the amount of our product candidates required in clinical trials, we may be unable to increase production in our unaffected facilities to meet demand. If the efficient manufacture and supply of our products or product candidates is interrupted, we may experience delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends, contract disputes and/or recalls of our products. From time to time we have initiated recalls of certain lots of our products. For example, in July 2014 we initiated a voluntary recall of an Aranesp® lot distributed in the EU after particles were detected in a quality control sample following distribution of that lot, and in April 2018 we initiated a precautionary recall of two batches of Vectibix® distributed in Switzerland after potential crimping defects were discovered in the metal seals on the product vials. If we are at any time unable to provide an uninterrupted supply of our products to patients,

we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could have a material adverse effect on our product sales, business and results of operations.

Our manufacturing processes, those of our third-party contract manufacturers and those of certain of our third-party service providers must undergo regulatory approval processes and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build, validate and license another manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer or service provider. If we elect or are required to make changes to our manufacturing processes because of new regulatory requirements, new interpretations of existing requirements or other reasons, this could increase our manufacturing costs and result in delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends or contract negotiations or disputes. Such manufacturing challenges may also occur if our existing contract manufacturers are unable or unwilling to implement such changes.

If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations or if authorities restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. Such issues may also delay the approval of product candidates we have submitted for regulatory review, even if such product candidates are not directly related to the products, devices or processes at issue with regulators. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, delays in our clinical trials, supply constraints, contract disputes, stock-outs and/or recalls of our products. Additionally, we distribute a substantial volume of our commercial products through our primary distribution centers in Louisville, Kentucky for the United States and in Breda, Netherlands for Europe and much of the rest of the world. We also conduct all the labeling and packaging of our products distributed in Europe and much of the rest of the world in Breda. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers, our third-party logistics providers and our labeling and packaging facility in Breda. Further, we rely on commercial transportation, including air and sea freight, for the distribution of our products to our customers, which may be negatively impacted by natural disasters or security threats.

Concentration of sales at certain of our wholesaler distributors and at one free-standing dialysis clinic business and consolidation of private payers may negatively impact our business.

Certain of our distributors, customers and payers have substantial purchasing leverage, due to the volume of our products they purchase or the number of patient lives for which they provide coverage. The substantial majority of our U.S. product sales is made to three pharmaceutical product wholesaler distributors: AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of our products, EPOGEN®, is sold primarily to free-standing dialysis clinics. DaVita owns or manages a large number of the outpatient dialysis facilities located in the United States and accounts for approximately 70% of all EPOGEN® sales. Similarly, as discussed above, there has been significant consolidation in the health insurance industry, including that a small number of PBMs now oversee a substantial percentage of total covered lives in the United States. See Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability. The three largest PBMs in the United States are now part of major health insurance providers. The growing concentration of purchasing and negotiating power by these entities may put pressure on our pricing due to their ability to extract price discounts on our products, fees for other services or rebates, negatively impacting our bargaining position, sales and/or profit margins. In addition, decisions by these entities to purchase or cover less or none of our products in favor of competitive products could have a material adverse effect on our product sales, business and results of operations due to their purchasing volume. Further, if one of our significant wholesale distributors encounters financial or other difficulties and becomes unable or unwilling to pay us all amounts that

such distributor owes us on a timely basis or at all, it could negatively impact our business and results of operations. In addition, if one of our significant wholesale distributors becomes insolvent or otherwise unable to continue its commercial relationship with us in its present form, it could significantly disrupt our business and adversely affect our product sales, our business and results of operations unless suitable alternatives are timely found or lost sales are absorbed by another distributor.

Our efforts to acquire other companies or products and to integrate their operations may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

We seek innovation through significant investment in both internal R&D and external transactions including collaborations, partnering, alliances, licenses, joint ventures, mergers and acquisitions (acquisition activity). We have an ongoing process of evaluating such potential acquisition activity opportunities that we expect will contribute to our future growth and expand our geographic footprint, product offerings and/or our R&D pipeline. Acquisitions or similar arrangements may be complex, time

consuming and expensive and may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may result in the diversion of our management's attention from other business issues and opportunities. We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, respectively. Failures or difficulties in integrating or retaining new personnel or in integrating the operations of the businesses we acquire (including their technology, compliance programs, distribution and general business operations and procedures), while preserving important R&D, distribution, marketing, promotion and other relationships, may affect our ability to grow and may result in our incurring asset impairment or restructuring charges.

Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.

As we continue our expansion efforts in emerging markets around the world, through acquisitions and licensing transactions as well as through the development and introduction of our products in new markets, we face numerous risks to our business. There is no guarantee that our efforts and strategies to expand sales in emerging markets will succeed. Emerging market countries may be especially vulnerable to periods of global and local political, legal, regulatory and financial instability, including sovereign debt issues and/or the imposition of international sanctions in response to certain state actions. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements previously utilized by companies we partner with or acquire in emerging markets. See We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications. As we expand internationally, we are subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar. While we have a program in place that is designed to reduce our exposure to foreign currency exchange rate fluctuations through foreign currency hedging arrangements, our hedging efforts do not completely offset the effect of these fluctuations on our revenues and earnings. Our international operations and business may also be subject to less protective intellectual property or other applicable laws, diverse data privacy and protection requirements, changing tax laws and tariffs, trade restrictions or other barriers designed to protect industry in the home country against foreign competition, far-reaching anti-bribery and anti-corruption laws and regulations and/or evolving legal and regulatory environments. These legal and operational challenges along with government controls, the challenges of attracting and retaining qualified personnel and obtaining and/or maintaining necessary regulatory or pricing approvals of our products may result in a material adverse impact on our international product sales, business and results of operations.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. Civil and criminal litigation is inherently unpredictable, and the outcome can result in costly verdicts, fines and penalties, exclusion from federal healthcare programs and/or injunctive relief that affect how we operate our business. Defense of litigation claims can be expensive, time consuming and distracting, and it is possible that we could incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our product sales, business and results of operations. In addition, product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and could adversely affect our reputation and the demand for our products. We and certain of our subsidiaries have previously been named as defendants in product liability actions for certain of our products.

We are also involved in government investigations that arise in the ordinary course of our business. In recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the United States and around the world. Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. We cannot ensure that all our employees, agents, contractors, vendors, licensees, partners or collaborators will comply with all applicable laws and regulations. In 2012, we finalized a settlement agreement with the U.S. government and various other parties to settle certain allegations regarding our

sales and marketing practices and agreed to operate under a corporate integrity agreement with the OIG of the U.S. Department of Health and Human Services, which was formally closed out in August 2018. We may see new government investigations of or actions against us citing novel theories of recovery. Any of these results could have a material adverse effect on our business and results of operations.

A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems and network-connected control systems and our data, interrupt the operation of our business and affect our reputation.

To achieve our business objectives, we rely to a large extent upon sophisticated information technology systems and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or affect our reputation.

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering and/or other means. Attacks such as those seen with other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access important data needed to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products in certain markets were negatively impacted. Our systems also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials or personal information belonging to us, our staff, our patients, customers and/or other business partners. In some cases, we utilize third-party service providers to process, store, manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) by employees, service providers, nation states, organized crime organizations, “hacktivists” or others, pose risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public. Finally, domestic and global government regulators, our key business partners, suppliers with whom we do business, companies that provide us or our partners with important business services and companies we may acquire may face similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. For example, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers.

Although in the past we have experienced system breakdowns, attacks and information security breaches, we do not believe such breakdowns, attacks and breaches have had a material adverse effect on our business or results of operations. We continue to invest in the monitoring, protection, and resilience of our critical or sensitive data and systems. However, there can be no assurance that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data, which could result in financial, legal, business or reputational harm to us or impact our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Our operations and performance have been, and may continue to be, affected by global economic conditions. Financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures. See Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients’ ability to afford health care as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, business and results of operations. Economic conditions may also adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors’, customers’ and suppliers’ financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could

have a material adverse effect on our product sales, business and results of operations.

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our consolidated balance sheets. The value of our investments may be adversely affected by interest rate fluctuations, downgrades in credit ratings, illiquidity in the capital markets and other factors that may result in other-than-temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments.

Our stock price is volatile.

Our stock price, like that of our peers in the biotechnology and pharmaceutical industries, is volatile. Our revenues and operating results may fluctuate from period to period for a number of reasons. Events such as a delay in product development, changes to our expectations or strategy or even a relatively small revenue shortfall may cause financial results for a period to be

below our expectations or projections. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Announcements or discussions, including via social media channels, of possible restrictive actions by government or private payers that would impact our business or industry if ultimately enacted or adopted may also cause our stock price to fluctuate, whether or not such restrictive actions ever actually occur. Similarly, actual or perceived safety issues with our products or similar products or unexpected clinical trial results can have an immediate and rapid impact on our stock price, whether or not our operating results are materially impacted.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The capital and credit markets may experience extreme volatility and disruption which may lead to uncertainty and liquidity issues for both borrowers and investors. We expect to access the capital markets to supplement our existing funds and cash generated from operations in satisfying our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in credit ratings issued by nationally recognized credit-rating agencies could adversely affect our ability to obtain capital market financing and the cost of such financing and have an adverse effect on the market price of our securities.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of December 31, 2018, we owned or leased approximately 190 properties. The locations and primary functions of significant properties are summarized in the following tables:

Excluded from the information above are (i) undeveloped land and leased properties that have been abandoned and (ii) certain buildings that we still own but are no longer used in our business. There are no material encumbrances on our owned properties.

We believe that our facilities are suitable for their intended uses and, in conjunction with our third-party contracting manufacturing agreements, provide adequate capacity and are sufficient to meet our expected needs. See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

See Item 1. Business—Manufacturing, Distribution and Raw Materials.

Item 3. LEGAL PROCEEDINGS

Certain of the legal proceedings in which we are involved are discussed in Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements, and are hereby incorporated by reference.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common stock

Our common stock trades on the NASDAQ Global Select Market under the symbol AMGN. As of February 7, 2019, there were approximately 5,760 holders of record of our common stock.

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2013, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index (S&P 500). All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.

Amgen vs. Amex Biotech, Amex Pharmaceutical and S&P 500 Indices

Comparison of Five-Year Cumulative Total Return

Value of Investment of $100 on December 31, 2013

| | 12/31/2013 | 12/31/2014 | 12/31/2015 | 12/31/2016 | 12/31/2017 | 12/31/2018 |
|---|---|---|---|---|---|---|
| Amgen (AMGN) | $100.00 | $142.32 | $147.97 | $136.80 | $167.33 | $192.57 |
| Amex Biotech (BTK) | $100.00 | $147.91 | $164.76 | $133.21 | $183.58 | $184.07 |
| Amex Pharmaceutical (DRG) | $100.00 | $116.58 | $121.45 | $111.32 | $129.83 | $139.50 |
| S&P 500 (SPX) | $100.00 | $113.68 | $115.24 | $129.02 | $157.26 | $150.39 |

The material in this performance graph is not soliciting material, is not deemed filed with the SEC, and is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

Stock repurchase program

During the three months and year ended December 31, 2018, we had one outstanding stock repurchase program, under which the repurchasing activity was as follows:

| | Total number of shares purchased | Average price paid per share[1] | Total number of shares purchased as part of publicly announced program | Maximum dollar value that may yet be purchased under the program[2] |
|---|---|---|---|---|
| October 1 - October 31 | 4,151,700 | $ 198.37 | 4,151,700 | $2,855,891,358 |
| November 1 - November 30 | 2,461,000 | $ 195.19 | 2,461,000 | $2,375,524,842 |
| December 1 - December 31 | 4,508,700 | $ 190.99 | 4,508,700 | $5,114,429,813 |
| | 11,121,400 | $ 194.67 | 11,121,400 | |
| January 1 - December 31 | 94,473,223 | $ 189.00 | 94,473,223 | |

(1) Average price paid per share includes related expenses.

(2) In December 2018, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $3.6 billion.

Dividends

For the years ended December 31, 2018 and 2017, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors. Additional information required by this item is incorporated herein by reference to Part IV—Note 17, Stockholders' equity, to the Consolidated Financial Statements.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

Information about securities authorized for issuance under existing equity compensation plans is incorporated by reference from Item 12—Securities Authorized for Issuance Under Existing Equity Compensation Plans.

Item 6. SELECTED FINANCIAL DATA

| | Years ended December 31, | | | | |
|---|---|---|---|---|---|
| Consolidated Statements of Income Data: | 2018 | 2017 | 2016 | 2015 | 2014 |
| | (In millions, except per-share data) | | | | |
| Revenues: | | | | | |
| Product sales | $22,533 | $21,795 | $21,892 | $20,944 | $19,327 |
| Other revenues | 1,214 | 1,054 | 1,099 | 718 | 736 |
| Total revenues | $23,747 | $22,849 | $22,991 | $21,662 | $20,063 |
| Operating expenses: | | | | | |
| Cost of sales | $4,101 | $4,069 | $4,162 | $4,227 | $4,422 |
| Research and development | $3,737 | $3,562 | $3,840 | $4,070 | $4,297 |
| Selling, general and administrative | $5,332 | $4,870 | $5,062 | $4,846 | $4,699 |
| Net income[1] | $8,394 | $1,979 | $7,722 | $6,939 | $5,158 |
| Diluted earnings per share[1] | $12.62 | $2.69 | $10.24 | $9.06 | $6.70 |
| Dividends paid per share | $5.28 | $4.60 | $4.00 | $3.16 | $2.44 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| Consolidated Balance Sheets Data: | 2018 | 2017 | 2016 | 2015 | 2014 |
| | (In millions) | | | | |
| Total assets | $66,416 | $79,954 | $77,626 | $71,449 | $68,882 |
| Total debt[2] | $33,929 | $35,342 | $34,596 | $31,429 | $30,588 |
| Total stockholders' equity[3] | $12,500 | $25,241 | $29,875 | $28,083 | $25,778 |

In addition to the following notes, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, Part IV—Consolidated Financial Statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our consolidated results of operations and financial position for periods reported therein and for known factors that will affect the comparability of future results. Also see Part IV—Note 17, Stockholders' equity, to the Consolidated Financial Statements, for information regarding cash dividends declared per share of common stock for each of the four quarters of 2018, 2017 and 2016. In addition, our Board of Directors declared dividends per share of $0.79 and $0.61 that were paid in each of the four quarters of 2015 and 2014, respectively.

(1) In 2017, we recorded a net charge of $6.1 billion as a result of the 2017 Tax Act. See Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

(2) See Part IV—Note 16, Financing arrangements, to the Consolidated Financial Statements, for discussion of our financing arrangements. In 2015, we issued $3.5 billion of debt and repaid $2.4 billion of debt. In 2014, we issued $4.5 billion of debt and repaid $5.6 billion of debt.

(3) Throughout the five years ended December 31, 2018, we had a stock repurchase program authorized by the Board of Directors, through which we repurchased $17.9 billion, $3.1 billion, $3.0 billion, $1.9 billion and $0.2 billion, respectively, of Amgen common stock.

## Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis (MD&A) is intended to assist the reader in understanding Amgen's business. MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying notes. Our results of operations discussed in MD&A are presented in conformity with U.S. generally accepted accounting principles (GAAP). Amgen operates in one business segment: human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

### Forward-looking statements

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward-looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume," and "contin variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and they involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Part I, Item 1A. Risk Factors. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecasted by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, earnings per share (EPS), liquidity and capital resources, trends, planned dividends, stock repurchases and restructuring plans. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen is a highly focused biotechnology company committed to unlocking the potential of biology for patients suffering from serious illnesses. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Our principal products—those with the most significant annual commercial sales—are ENBREL, Neulasta®, Prolia®, Aranesp®, XGEVA®, Sensipar®/Mimpara® and EPOGEN®. We also market a number of other products, including KYPROLIS®, Nplate®, Vectibix®, Repatha®, NEUPOGEN®, Parsabiv®, BLINCYTO®, Aimovig®, IMLYGIC®, Corlanor®, KANJINTI™ and AMGEVITA™. For additional information about our products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products.

Our strategy includes a set of integrated activities intended to maintain and strengthen our competitive position in the industry. In 2018, we advanced our strategy while delivering strong financial performance and returning capital to shareholders, advancing our innovative pipeline and branded biosimilar programs, increasing our global geographic reach and expanding our next-generation manufacturing capabilities.

In 2018, total product sales increased 3% driven primarily by Prolia®, XGEVA®, Repatha® and KYPROLIS®, along with our recently launched products Aimovig® and Parsabiv®. Product sales grew 2% in the United States and 9% in the rest of the world. Total operating expenses increased 5% as we supported our recently launched products and R&D pipeline, including early oncology assets. Cash inflows from operating activities were $11.3 billion, enabling us to invest in our business while returning capital to shareholders through the payment of cash dividends and stock repurchases. We increased our quarterly cash dividend by 15% to $1.32 per share of common stock. In December 2018, we declared a cash dividend of $1.45 per share of common stock for the first quarter of 2019, an increase of 10% for this period, to be paid in March 2019. We also repurchased 94.5 million shares of our common stock throughout 2018 at an aggregate cost of $17.9 billion.

In addition to launching Aimovig® in the United States and Parsabiv® in the United States and the EU, we received approvals for new indications for Repatha® and Prolia®, along with KYPROLIS®, BLINCYTO®, XGEVA® and Nplate® within our oncology/hematology portfolio. We continued to strengthen our international footprint with the approvals of Repatha® in China, and in early 2019, EVENITY™ in Japan. In addition to these commercial products, we continue to advance our pipeline of innovative first-in-class molecules, including our phase 3 molecule, tezepelumab. The FDA granted Breakthrough Therapy Designation for tezepelumab in patients with severe asthma without an eosinophilic phenotype. We have also continued to invest in external innovation to augment our internal innovation with a focus when possible, on genetic related investments and genetically validated targets.

We also continued to advance our biosimilar program with the approval of MVASI™ for the treatment of five types of cancer in the United States and the EU, and the launches of KANJINTI™ and AMGEVITA™ in Europe. Lastly, we made regulatory submissions for ABP 710 in the United States and the EU.

We broke ground on our new next-generation biomanufacturing plant in Rhode Island in 2018. This new plant will be the first of its kind in the United States and will use our proven next-generation biomanufacturing capabilities to manufacture our products while maintaining a reliable, high-quality, compliant supply of medicines. Next-generation biomanufacturing plants require a smaller manufacturing footprint and offer greater environmental benefits, including reduced consumption of water and energy and lower levels of carbon emissions. Our first next-generation biomanufacturing facility located in Singapore is already in use for certain commercial-scale production for multiple countries.

While 2018 execution was strong, we face competition on our more mature products. We have established productivity initiatives to enable investment in new products and the defense of existing products to optimize long- and short-term growth.

Our long-term success depends, to a great extent, on our ability to continue to discover, develop and commercialize innovative products and acquire or collaborate on therapies currently in development by other companies. We must develop new products over time in order to provide for revenue growth and to offset revenue losses when products lose their exclusivity or competing products are launched. Certain of our products face increasing pressure from competition, including biosimilars and generics. For additional information, including information on the expiration of

patents for various products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Patents and see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition.

We devote considerable resources to R&D activities. However, successful product development in the biotechnology industry is highly uncertain. We are also confronted by increasing regulatory scrutiny of safety and efficacy both before and after products launch.

Rising healthcare costs and economic conditions also continue to pose challenges to our business, including continued pressure by third-party payers, such as governments and private payers, to reduce healthcare expenditures. As a result of public

and private health care provider focus, the industry continues to experience significant pricing pressures and other cost containment measures. Finally, wholesale and end-user buying patterns can affect our product sales. These effects can cause fluctuations in quarterly product sales and have generally not been significant when comparing full-year product performance to the prior year. See Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products and Part I, Item 1A. Risk Factors for further discussion of certain of the factors that could impact our future product sales.

Selected Financial Information

The following is an overview of our results of operations (in millions, except percentages and per-share data):

| | Year ended December 31, 2018 | Change | | Year ended December 31, 2017 |
|---|---|---|---|---|
| Product sales: | | | | |
| U.S. | $ 17,429 | 2 | % | $ 17,131 |
| Rest of world (ROW) | 5,104 | 9 | % | 4,664 |
| Total product sales | 22,533 | 3 | % | 21,795 |
| Other revenues | 1,214 | 15 | % | 1,054 |
| Total revenues | $ 23,747 | 4 | % | $ 22,849 |
| Operating expenses | $ 13,484 | 5 | % | $ 12,876 |
| Operating income | $ 10,263 | 3 | % | $ 9,973 |
| Net income | $ 8,394 | * | | $ 1,979 |
| Diluted EPS | $ 12.62 | * | | $ 2.69 |
| Diluted shares | 665 | (10 | )% | 735 |

* Change in excess of 100%

In the following discussion of changes in product sales, any reference to unit demand growth or decline refers to changes in the purchases of our products by healthcare providers (such as physicians or their clinics), dialysis centers, hospitals and pharmacies. In addition, any reference to increases or decreases in inventory refers to changes in inventory held at wholesaler customers and end-users (such as pharmacies).

Total product sales increased for 2018, driven primarily by higher unit demand, offset partially by a decline in net selling price. For 2019, we expect net selling price to continue to decline.

Other revenues increased for 2018, driven primarily by higher milestone payments and royalties.

Operating expenses increased for 2018, driven primarily by investments in product launches and increased spend in R&D, including support of our early pipeline. All expense categories continued to benefit from our transformation and process improvement efforts, which enabled investment in newer and recently launched products.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material in 2018, 2017 or 2016.

Results of Operations

Product sales

Worldwide product sales were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| ENBREL | $ 5,014 | (8)% | $ 5,433 | (9)% | $ 5,965 |
| Neulasta® | 4,475 | (1)% | 4,534 | (2)% | 4,648 |
| Prolia® | 2,291 | 16 % | 1,968 | 20 % | 1,635 |
| Aranesp® | 1,877 | (9)% | 2,053 | (2)% | 2,093 |
| XGEVA® | 1,786 | 13 % | 1,575 | 3 % | 1,529 |
| Sensipar®/Mimpara® | 1,774 | 3 % | 1,718 | 9 % | 1,582 |
| EPOGEN® | 1,010 | (8)% | 1,096 | (15)% | 1,282 |
| Other products | 4,306 | 26 % | 3,418 | 8 % | 3,158 |
| Total product sales | $ 22,533 | 3 % | $ 21,795 | — % | $ 21,892 |
| Total U.S. | $ 17,429 | 2 % | $ 17,131 | (1)% | $ 17,325 |
| Total ROW | 5,104 | 9 % | 4,664 | 2 % | 4,567 |
| Total product sales | $ 22,533 | 3 % | $ 21,795 | — % | $ 21,892 |

Future sales of our products will depend, in part, on the factors discussed in the Overview, Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition, in Part I, Item 1A. Risk Factors, and any additional factors discussed in the individual product sections below. In addition, for a list of our products' significant competitors, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—Competition.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| ENBREL — U.S. | $ 4,807 | (8)% | $ 5,206 | (9)% | $ 5,719 |
| ENBREL — Canada | 207 | (9)% | 227 | (8)% | 246 |
| Total ENBREL | $ 5,014 | (8)% | $ 5,433 | (9)% | $ 5,965 |

The decrease in ENBREL sales for 2018 was driven primarily by lower unit demand and net selling price.

The decrease in ENBREL sales for 2017 was driven primarily by lower unit demand and net selling price, offset partially by an increase in inventory.

For 2019, we expect the trend of lower unit demand to continue.

Multiple companies are developing proposed biosimilar versions of ENBREL, and we are involved in patent litigation with the company seeking to market the biosimilar version of ENBREL approved by the FDA in 2016. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

Neulasta®

Total Neulasta® sales by geographic region were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| Neulasta® — U.S. | $ 3,866 | (2)% | $ 3,931 | — % | $ 3,925 |
| Neulasta® — ROW | 609 | 1 % | 603 | (17)% | 723 |
| Total Neulasta® | $ 4,475 | (1)% | $ 4,534 | (2)% | $ 4,648 |

The decrease in global Neulasta® sales for 2018 was driven primarily by favorable changes in accounting estimates of product returns in 2017, offset partially by favorable changes in inventory. Neulasta® sales for 2018 included a $55 million order in the fourth quarter from the U.S. government.

The decrease in global Neulasta® sales for 2017 was driven primarily by lower unit demand, offset partially by an increase in net selling price in the United States.

Neulasta® sales have been and will continue to be affected by the development of new protocols, tests and/or treatments for cancer and/or new treatment alternatives, including those that have reduced and may continue to reduce the use of myelosuppressive regimens in some patients.

Our final material U.S. patent for Neulasta® expired in October 2015. Therefore, we face competition in the United States, which over time may have a material adverse impact on future sales of Neulasta®. A biosimilar version of Neulasta® was approved in the second quarter of 2018 and launched in July 2018, and another biosimilar version was approved in the fourth quarter of 2018 and launched in January 2019. Other biosimilar versions of Neulasta® may also receive approval in the near future. For a discussion of ongoing patent litigations with these and other companies that are developing proposed biosimilar versions of Neulasta®, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

In addition, supplementary protection certificates issued by certain countries, including France, Germany, Italy, Spain and the United Kingdom, that are related to our European patent for Neulasta® expired in August 2017. In 2019, we expect European sales to decline with the launch of multiple long-acting biosimilar competitors.

Prolia®

Total Prolia® sales by geographic region were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| Prolia® — U.S. | $ 1,500 | 18 % | $ 1,272 | 21 % | $ 1,049 |
| Prolia® — ROW | 791 | 14 % | 696 | 19 % | 586 |
| Total Prolia® | $ 2,291 | 16 % | $ 1,968 | 20 % | $ 1,635 |

The increases in global Prolia® sales for 2018 and 2017 were driven primarily by higher unit demand.

Aranesp®

Total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| Aranesp® — U.S. | $ 942 | (15)% | $ 1,114 | 3 % | $ 1,082 |
| Aranesp® — ROW | 935 | — % | 939 | (7)% | 1,011 |
| Total Aranesp® | $ 1,877 | (9)% | $ 2,053 | (2)% | $ 2,093 |

The decrease in global Aranesp® sales for 2018 was driven primarily by the impact of competition on unit demand.

The decrease in global Aranesp® sales for 2017 was driven primarily by unfavorable changes in foreign currency exchange rates, offset partially by higher unit demand, including a shift of some U.S. dialysis centers from

EPOGEN®.

Aranesp® faces competition from a long-acting product. Aranesp® also faces competition from a biosimilar version of EPOGEN®, which was approved in the second quarter of 2018 and launched in the fourth quarter of 2018. Other biosimilar versions of EPOGEN ® may also receive approval. In 2019, we expect sales in the United States to decline at a faster rate than 2018 due to short- and long- acting competition.

XGEVA®

Total XGEVA® sales by geographic region were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| XGEVA® — U.S. | $ 1,338 | 16 % | $ 1,157 | 4 % | $ 1,115 |
| XGEVA® — ROW | 448 | 7 % | 418 | 1 % | 414 |
| Total XGEVA® | $ 1,786 | 13 % | $ 1,575 | 3 % | $ 1,529 |

The increases in global XGEVA® sales for 2018 and 2017 were driven primarily by higher unit demand.

Sensipar®/Mimpara®

Total Sensipar®/Mimpara® sales by geographic region were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| Sensipar® — U.S. | $ 1,436 | 5 % | $ 1,374 | 11 % | $ 1,240 |
| Sensipar®/Mimpara® — ROW | 338 | (2 )% | 344 | 1 % | 342 |
| Total Sensipar®/Mimpara® | $ 1,774 | 3 % | $ 1,718 | 9 % | $ 1,582 |

The increase in global Sensipar®/Mimpara® sales for 2018 was driven primarily by an increase in net selling price in the United States, offset partially by lower unit demand.

The increase in global Sensipar®/Mimpara® sales for 2017 was driven primarily by an increase in net selling price in the United States and, to a lesser extent, higher unit demand.

Our U.S. composition of matter patent related to Sensipar®, a small molecule, expired in March 2018. We are involved in patent litigation with a number of companies seeking to market generic versions of Sensipar®, one of which began selling its generic version in late December 2018 until reaching a settlement agreement with us in early January 2019. In a separate litigation, we have been sued by the manufacturer of another approved generic version of Sensipar® who is contending that provisions of its own settlement agreement with Amgen have been triggered by the first manufacturer's at-risk launch, giving this second manufacturer a right to market its own generic version under its settlement agreement. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

In 2019, we expect Sensipar® sales will be lower than 2018 due to the temporary generic market entry, continued adoption of Parsabiv® and higher purchases in 2018 due to the reimbursement change from Medicare Part D to Part B. Further, generic competitors may enter the market at risk at any time.

EPOGEN®

Total EPOGEN® sales were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| EPOGEN® — U.S. | $ 1,010 | (8 )% | $ 1,096 | (15 )% | $ 1,282 |

The decrease in EPOGEN® sales for 2018 was driven primarily by a decline in net selling price due to contractual terms negotiated with DaVita (see Part I, Item I. Business—Business Relationships). In 2019, we expect a more significant decline in net selling price.

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The decrease in EPOGEN® sales for 2017 was driven primarily by a decline in net selling price due to contractual terms negotiated with DaVita and, to a lesser extent, a shift in some U.S. dialysis centers to Aranesp®.

Our final material U.S. patent for EPOGEN® expired in May 2015. We face competition in the United States, which has had and will continue to have a material adverse impact on sales of EPOGEN ®. Multiple companies are developing proposed biosimilar versions of EPOGEN ®. A biosimilar version of EPOGEN ® was approved in the second quarter of 2018 and launched in the fourth quarter of 2018. Other biosimilar versions of EPOGEN ® may also receive approval. For a discussion of ongoing patent litigation with one of these companies, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

Other products

Other product sales by geographic region were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| KYPROLIS® — U.S. | $ 583 | 4 % | $ 562 | 1 % | $ 554 |
| KYPROLIS® — ROW | 385 | 41 % | 273 | 98 % | 138 |
| Nplate® — U.S. | 438 | 12 % | 392 | 12 % | 350 |
| Nplate® — ROW | 279 | 12 % | 250 | 7 % | 234 |
| Vectibix® — U.S. | 288 | 15 % | 251 | 10 % | 229 |
| Vectibix® — ROW | 403 | 3 % | 391 | 2 % | 382 |
| Repatha® — U.S. | 358 | 59 % | 225 | * | 101 |
| Repatha® — ROW | 192 | * | 94 | * | 40 |
| NEUPOGEN® — U.S. | 223 | (40 )% | 369 | (31 )% | 534 |
| NEUPOGEN® — ROW | 142 | (21 )% | 180 | (22 )% | 231 |
| Parsabiv® — U.S. | 302 | * | — | — % | — |
| Parsabiv® — ROW | 34 | * | 5 | * | — |
| BLINCYTO® — U.S. | 134 | 18 % | 114 | 34 % | 85 |
| BLINCYTO® — ROW | 96 | 57 % | 61 | * | 30 |
| Aimovig® — U.S. | 119 | * | — | — % | — |
| Biosimilars — ROW | 55 | * | — | — % | — |
| Other — U.S. | 85 | 25 % | 68 | 13 % | 60 |
| Other — ROW | 190 | 4 % | 183 | (4 )% | 190 |
| Total other product sales | $ 4,306 | 26 % | $ 3,418 | 8 % | $ 3,158 |
| Total U.S. — other products | $ 2,530 | | $ 1,981 | | $ 1,913 |
| Total ROW — other products | 1,776 | | 1,437 | | 1,245 |
| Total other product sales | $ 4,306 | | $ 3,418 | | $ 3,158 |

* Change in excess of 100%

Operating expenses

Operating expenses were as follows (dollar amounts in millions):

| | Year ended December 31, 2018 | Change | Year ended December 31, 2017 | Change | Year ended December 31, 2016 |
|---|---|---|---|---|---|
| Operating expenses: | | | | | |
| Cost of sales | $ 4,101 | 1 % | $ 4,069 | (2 )% | $ 4,162 |
| % of product sales | 18.2 % | | 18.7 % | | 19.0 % |
| % of total revenues | 17.3 % | | 17.8 % | | 18.1 % |
| Research and development | $ 3,737 | 5 % | $ 3,562 | (7 )% | $ 3,840 |
| % of product sales | 16.6 % | | 16.3 % | | 17.5 % |
| % of total revenues | 15.7 % | | 15.6 % | | 16.7 % |
| Selling, general and administrative | $ 5,332 | 9 % | $ 4,870 | (4 )% | $ 5,062 |
| % of product sales | 23.7 % | | 22.3 % | | 23.1 % |
| % of total revenues | 22.5 % | | 21.3 % | | 22.0 % |
| Other | $ 314 | (16 )% | $ 375 | * | $ 133 |

* Change in excess of 100%

Transformation and process improvement

During 2014, we announced transformation and process improvement efforts that we continue to execute. As part of these efforts, we committed to a more agile and efficient operating model. Our transformation and process improvement efforts across the Company are enabling us to reallocate resources to fund many of our innovative pipeline and growth opportunities that deliver value to patients and stockholders.

The transformation included a restructuring plan, and the activities associated with the restructuring plan have been completed. As of December 31, 2018, restructuring costs incurred to date were $809 million. During 2018, 2017 and 2016, we incurred restructuring costs of $12 million, $88 million and $37 million, respectively. Since 2014, we have realized approximately $1.9 billion of transformation and process improvement savings. Net savings have not been significant as savings were reinvested in product launches, clinical programs and external business development. Additional information required for our restructuring plan is incorporated herein by reference to Part IV—Note 2, Restructuring, to the Consolidated Financial Statements.

Cost of sales

Cost of sales decreased to 17.3% of total revenues for 2018, driven primarily by lower royalty costs, expenses related to Hurricane Maria in 2017 and lower acquisition-related amortization of intangible assets, offset partially by higher manufacturing costs.

Cost of sales decreased to 17.8% of total revenues for 2017, driven primarily by lower acquisition-related amortization of intangible assets, lower royalty costs and favorable manufacturing costs, offset partially by expenses related to Hurricane Maria, unfavorable product mix and other inventory costs.

Research and development

The Company groups all of its R&D activities and related expenditures into three categories: (1) Research and early pipeline (formerly Discovery Research and Translational Sciences), (2) later-stage clinical programs and (3) marketed products. These categories are described below:

| Category | Description |
|---|---|
| Research and early pipeline | R&D expenses incurred in activities substantially in support of early research through the completion of phase 1 clinical trials, including drug discovery, toxicology, pharmacokinetics and drug metabolism, and process development. |
| Later-stage clinical programs | R&D expenses incurred in or related to phase 2 and phase 3 clinical programs intended to result in registration of a new product or a new indication for an existing product in the United States or the EU. |
| Marketed products | R&D expenses incurred in support of the Company's marketed products that are authorized to be sold in the United States or the EU. Includes clinical trials designed to gather information on product safety (certain of which may be required by regulatory authorities) and their product characteristics after regulatory approval has been obtained, as well as the costs of obtaining regulatory approval of a product in a new market after approval in either the United States or the EU has been obtained. |

R&D expense by category was as follows (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Research and early pipeline | $1,201 | $972 | $1,039 |
| Later-stage clinical programs | 1,034 | 879 | 1,054 |
| Marketed products | 1,502 | 1,711 | 1,747 |
| Total R&D expense | $3,737 | $3,562 | $3,840 |

The increase in R&D expense for 2018 was driven by higher spend on our early pipeline, later-stage clinical programs as well as external business development expense in research and early pipeline, offset partially by lower marketed product support.

The decrease in R&D expense for 2017 was driven by decreased costs associated with later-stage clinical program support, lower external business development expense in research and early pipeline and lower marketed product support.

Selling, general and administrative

The increase in Selling, general and administrative (SG&A) expense for 2018 was driven primarily by investments in product launches and marketed product support.

The decrease in SG&A expense for 2017 was driven primarily by the expiration of the ENBREL residual royalty payments on October 31, 2016, offset partially by investments in product launches and marketed product support.

The ENBREL co-promotion term expired in October 2013, and we were required to pay Pfizer residual royalties on a declining percentage of ENBREL net sales in the United States and Canada. Effective November 2016, there were no further residual royalty payments. The residual royalty percentage ranged from 10% to 11% in 2016.

Other

Other operating expenses for 2018 included a $330 million impairment charge associated with an intangible asset acquired in a business combination and a $42 million favorable net change in the fair values of contingent consideration. See Part IV—Note 14, Goodwill and other intangible assets, to the Consolidated Financial Statements.

Other operating expenses for 2017 included $284 million of impairment-related charges associated with an intangible asset acquired in a business combination and $83 million of certain net charges related to our restructuring plan.

Other operating expenses for 2016 included $105 million of charges related to legal proceedings.

Nonoperating expenses/income and income taxes

Nonoperating expenses/income and income taxes were as follows (dollar amounts in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Interest expense, net | $1,392 | $1,304 | $1,260 |
| Interest and other income, net | $674 | $928 | $629 |
| Provision for income taxes | $1,151 | $7,618 | $1,441 |
| Effective tax rate | 12.1 % | 79.4 % | 15.7 % |

Interest expense, net

The increase in Interest expense, net, for 2018 was due primarily to the impact of rising interest rates on variable-rate debt.

The increase in Interest expense, net, for 2017 was due primarily to a higher average amount of debt outstanding compared with the prior year.

Interest and other income, net

The decrease in Interest and other income, net, for 2018 was due primarily to higher investment losses and lower interest income as a result of the liquidation of a portion of our portfolio, offset partially by gains on our equity investments and a net gain recognized in connection with our acquisition of K-A in the first quarter of 2018. See Part IV—Note 3, Business combinations, to the Consolidated Financial Statements.

The increase in Interest and other income, net, for 2017 was due primarily to higher interest income that resulted from higher average investment balances and higher gains on strategic investments.

Income taxes

The decrease in our effective tax rate for 2018 compared with 2017 was due primarily to impacts of U.S. corporate tax reform.

On December 22, 2017, the United States enacted the 2017 Tax Act, which imposes a repatriation tax on accumulated earnings of foreign subsidiaries, imposes a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We have completed our accounting for the tax effects of the 2017 Tax Act, including the repatriation tax, the net deferred tax remeasurement and the impact on our unrealized tax benefits. None of the adjustments we made to our provisional amounts were material to our consolidated financial statements.

As previously disclosed, we received a RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

See Summary of Critical Accounting Policies—Income taxes, and Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows (in millions):

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Cash, cash equivalents and marketable securities | $29,304 | $41,678 |
| Total assets | $66,416 | $79,954 |
| Current portion of long-term debt | $4,419 | $1,152 |
| Long-term debt | $29,510 | $34,190 |
| Stockholders' equity | $12,500 | $25,241 |

Cash, cash equivalents and marketable securities

We have global access to our $29.3 billion balance of cash, cash equivalents and marketable securities, as we no longer reinvest the related undistributed foreign earnings indefinitely outside the United States. As a result of the 2017 Tax Act, we recorded a repatriation tax liability on undistributed earnings generated from operations in foreign tax jurisdictions estimated at $7.3 billion, which will be paid over eight years. The first annual payment was made in April 2018. See Contractual Obligations below.

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings and places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

Consistent with the objective to optimize our capital structure, we seek to deploy our accumulated cash balances in an efficient manner, and we consider several alternatives such as payment of dividends, stock repurchases, repayment of debt, and strategic transactions that expand our portfolio of products in areas of therapeutic interest.

We intend to continue to invest in our business and return capital to stockholders through the payment of cash dividends and stock repurchases reflecting our confidence in the future cash flows of our business. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, the availability of financing on acceptable terms, debt service requirements, our credit rating, changes to applicable tax laws or corporate laws, changes to our business model and periodic determination by our Board of Directors that cash dividends and/or stock repurchases are in the best interests of stockholders and are in compliance with applicable laws and agreements of the Company. In addition, the timing and amount of stock repurchases may also be affected by the stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

The Board of Directors declared quarterly cash dividends of $1.00 per share of common stock paid in 2016, increased our quarterly cash dividend by 15% to $1.15 per share of common stock paid in 2017, and increased our quarterly cash dividend by 15% to $1.32 per share of common stock paid in 2018. In December 2018, the Board of Directors declared a cash dividend of $1.45 per share of common stock for the first quarter of 2019, an increase of 10% for this period, to be paid in March 2019.

We have also returned capital to stockholders through our stock repurchase program. During 2018, we repurchased $17.9 billion of common stock and had cash settlements of $17.8 billion, which included 52.1 million shares of common stock repurchased through a $10.0 billion tender offer. In 2017 and 2016, we repurchased $3.1 billion and $3.0 billion of our common stock, respectively. As of December 31, 2018, $5.1 billion remained available under the stock repurchase program.

As a result of stock repurchases, including our recent tender offer, and quarterly dividend payments, we have an accumulated deficit as of December 31, 2018 and 2017. Our accumulated deficit is not expected to affect our future ability to operate, repurchase stock, pay dividends or repay our debt given our continuing profitability and strong financial position.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt

markets and equity markets. See Part I, Item 1A. Risk Factors—Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Financing arrangements

The current and noncurrent portions of our long-term borrowings as of December 31, 2018, were $4.4 billion and $29.5 billion, respectively. The current and noncurrent portions of our long-term borrowings as of December 31, 2017, were $1.2 billion and $34.2 billion, respectively. As of December 31, 2018, Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's) and Fitch Ratings Inc. (Fitch) assigned credit ratings to our outstanding senior notes of A with a stable outlook, Baa1 with a stable outlook and BBB with a stable outlook, respectively, which are considered investment grade. Unfavorable changes to these ratings may have an adverse impact on future financings.

During 2018, we did not issue any debt or debt securities. During 2017 and 2016, we issued debt with aggregate principal amounts of $4.5 billion and $7.3 billion, respectively. During 2018, 2017 and 2016, we repaid debt of $1.1 billion, $4.4 billion and $3.7 billion, respectively.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating London Interbank Offered Rates (LIBOR)-based coupon over the life of the respective note. These interest rate swap contracts qualify and are designated as fair value hedges. As of December 31, 2018 and 2017, we had interest rate swap contracts with aggregate notional amounts of $10.95 billion and $9.45 billion, respectively.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively convert the interest payments and principal repayment of the respective notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts qualify and are designated as cash flow hedges. As of December 31, 2018 and 2017, we had cross-currency swap contracts with aggregate notional amounts of $5.6 billion.

As of December 31, 2018, we had a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During 2017, we issued and repaid an aggregate of $12.3 billion commercial paper and had a maximum outstanding balance of $1.5 billion under our commercial paper program. During 2018 and 2016, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2018 or 2017.

In 2014, we entered into a $2.5 billion syndicated, unsecured, revolving credit agreement which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $500 million with the agreement of the banks. Each bank which is a party to the agreement has an initial commitment term of five years. We extended this term by one year during 2016 and may extend the term for an additional year with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest at LIBOR plus 1% for any amounts borrowed under this facility. As of December 31, 2018 and 2017, no amounts were outstanding under this facility.

In 2017, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2020.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which was modified during 2018. The modified covenant requires that we maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest expense, each as defined and described in the amended credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2018.

See Part IV—Note 16, Financing arrangements, and Note 19, Derivative instruments, to the Consolidated Financial Statements.

Cash flows

Our summarized cash flow activity was as follows (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Net cash provided by operating activities | $11,296 | $11,177 | $10,354 |
| Net cash provided by (used in) investing activities | $14,339 | $(4,024) | $(8,658) |
| Net cash used in financing activities | $(22,490) | $(6,594) | $(2,599) |

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities increased during 2018 due primarily to improvements in working capital, offset partially by higher payments to taxing authorities. Cash provided by operating activities increased during 2017 due primarily to higher operating margin and the timing of payments to vendors and receipts from customers, offset partially by higher payments to taxing authorities.

Investing

Cash provided by investing activities during 2018 was due primarily to net cash inflows related to marketable securities of $15.0 billion and cash used in investing activities during 2017 and 2016 was due primarily to net cash outflows related to marketable securities of $3.2 billion, and $7.7 billion, respectively. Capital expenditures, which were associated primarily with site development costs, including our Thousand Oaks campus, as well as the new next-generation biomanufacturing facility in Rhode Island and life-cycle investments across the manufacturing network, were $738 million, $664 million and $738 million in 2018, 2017 and 2016, respectively. We currently estimate 2019 spending on capital projects to be approximately $700 million.

Financing

Cash used in financing activities during 2018 was due primarily to repurchases of our common stock of $17.8 billion, the payment of dividends of $3.5 billion, repayment of debt of $1.1 billion and withholding taxes arising from shares withheld for share-based payments of $126 million. Cash used in financing activities during 2017 was due primarily to the payment of dividends of $3.4 billion, repurchases of our common stock of $3.2 billion and withholding taxes arising from shares withheld for share-based payments of $191 million, offset partially by proceeds from the issuance of debt, net of repayment, of $71 million. Cash used in financing activities during 2016 was due primarily to the payment of dividends of $3.0 billion, repurchases of our common stock of $3.0 billion and withholding taxes arising from shares withheld for share-based payments of $260 million, offset partially by proceeds from the issuance of debt, net of repayment, of $3.6 billion.

See Part IV—Note 16, Financing arrangements, and Note 17, Stockholders' equity, to the Consolidated Financial Statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are material or reasonably likely to become material to our consolidated financial position or consolidated results of operations.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information. Timing of payments and actual amounts paid may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations.

The following table represents our contractual obligations aggregated by type (in millions):

| | Payments due by period as of December 31, 2018 | | | | |
|---|---|---|---|---|---|
| Contractual obligations | Total | Year 1 | Years 2 and 3 | Years 4 and 5 | Years 6 and beyond |
| Long-term debt obligations [1] [2] [3] | $54,276 | $5,856 | $8,777 | $7,444 | $ 32,199 |
| Operating lease obligations [4] | 569 | 164 | 239 | 120 | 46 |
| Purchase obligations [5] | 1,153 | 609 | 305 | 124 | 115 |
| U.S. repatriation tax [6] | 6,739 | 586 | 1,172 | 1,685 | 3,296 |
| Unrecognized tax benefits (UTBs) [7] | — | — | — | — | — |
| Total contractual obligations | $62,737 | $7,215 | $10,493 | $9,373 | $ 35,656 |

(1) Long-term debt obligations include future interest payments on our fixed-rate obligations at the contractual coupon rates. To achieve a desired mix of fixed-rate and floating-rate debt, we enter into interest rate swap contracts that effectively convert a fixed-rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the terms of the related hedge contracts. We used an interest rate forward curve as of December 31, 2018, in computing net amounts to be paid or received under our interest rate swap contracts, which resulted in an aggregate net increase in future interest payments of $77 million. See Part IV—Note 16, Financing arrangements, to the Consolidated Financial Statements.

(2) Long-term debt obligations include future interest payments on our LIBOR-based variable-rate obligations. We used an interest rate forward curve as of December 31, 2018, in computing the LIBOR-based portion of interest payments on these debt obligations. See Part IV—Note 16, Financing arrangements, to the Consolidated Financial Statements.

(3) Long-term debt obligations include contractual interest payments and principal repayment of our foreign-denominated debt obligations. In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our euro-, pound-sterling- and Swiss-franc-denominated long-term debt, we enter into cross-currency swap contracts that effectively convert interest payments and principal repayment on this debt from euros, pounds sterling and Swiss francs to U.S. dollars. For purposes of this table, we used the contracted exchange rates in the cross-currency swap contracts to compute the net amounts of future interest payments and principal repayments on this debt. See Part IV—Note 19, Derivative instruments, to the Consolidated Financial Statements.

(4) Operating lease obligations exclude $203 million of future receipts under noncancelable subleases of abandoned facilities.

(5) Purchase obligations relate primarily to: (i) R&D commitments (including those related to clinical trials) for new and existing products; (ii) capital expenditures; and (iii) open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced based on certain future events.

(6) Under the 2017 Tax Act, we elected to pay the repatriation tax related primarily to our prior indefinitely invested earnings of our foreign operations in eight annual installments. See Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

(7) Liabilities for UTBs (net of foreign tax credits and federal tax benefit of state taxes) and related accrued interest and penalties of $2.6 billion as of December 31, 2018, are not included in the table above because, due to their nature, there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities.

In addition to amounts in the table above, we are contractually obligated to pay additional amounts, which in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, including contingent consideration incurred in the acquisition of K-A and BioVex Group Inc. (BioVex). These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring. These contingent payments have not been included in the table above, and, except with respect to the fair value of the contingent consideration obligations, are

not recorded on our Consolidated Balance Sheets. As of December 31, 2018, the maximum amount that may be payable in the future for agreements we have entered into with third parties is $7.5 billion, including $325 million of contingent consideration payments in connection with the acquisition of BioVex. Contingent consideration with respect to the acquisition of Dezima Pharma B.V. was excluded due to the discontinuation of the development of AMG 899, upon which payments are based. See Part IV—Note 18, Fair value measurement, to the Consolidated Financial Statements.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. Amounts recorded in Accrued liabilities in the Consolidated Balance Sheets for sales deductions were as follows (in millions):

| | Rebates | Chargebacks | Other deductions | Total |
|---|---|---|---|---|
| Balance as of December 31, 2015 | $1,119 | $ 273 | $ 94 | $1,486 |
| Amounts charged against product sales | 3,479 | 5,270 | 905 | 9,654 |
| Payments | (3,181) | (5,201) | (884) | (9,266) |
| Balance as of December 31, 2016 | 1,417 | 342 | 115 | 1,874 |
| Amounts charged against product sales | 4,909 | 6,098 | 992 | 11,999 |
| Payments | (4,459) | (6,168) | (999) | (11,626) |
| Balance as of December 31, 2017 | 1,867 | 272 | 108 | 2,247 |
| Amounts charged against product sales | 6,180 | 6,926 | 1,180 | 14,286 |
| Payments | (5,458) | (6,744) | (1,161) | (13,363) |
| Balance as of December 31, 2018 | $2,589 | $ 454 | $ 127 | $3,170 |

For the years ended December 31, 2018, 2017 and 2016, total sales deductions were 39%, 35% and 31% of gross product sales, respectively. The increase in the total sales deductions balance as of December 31, 2018 compared to December 31, 2017, was driven primarily by the impact of higher sales, increases in U.S. rebates and chargebacks, as well as timing of payments. Included in the amounts are immaterial net adjustments related to prior-year sales due to changes in estimates. Such amounts represent less than 1% of the aggregate sales deductions charged against product sales in the years ended December 31, 2016, 2017 and 2018.

In the United States, we utilize wholesalers as the principal means of distributing our products to healthcare providers, such as physicians or their clinics, dialysis centers, hospitals and pharmacies. Products we sell in Europe are distributed principally to hospitals and/or wholesalers depending on the distribution practice in each country where the products are sold. We monitor the inventory levels of our products at our wholesalers by using data from our wholesalers and other third parties, and we believe wholesaler inventories have been maintained at appropriate levels (generally two to three weeks) given end-user demand. Accordingly, historical fluctuations in wholesaler inventory levels have not significantly affected our method of estimating sales deductions and returns.

Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given year, can be affected by the mix of products sold.

Rebates include primarily amounts paid to payers and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements, which vary by product, by payer and by individual payer plans. As we sell products, we estimate the amount of rebate we will pay based on the product sold, contractual terms, estimated patient population, historical experience and wholesaler inventory levels, and we accrue these rebates in the period the related sales are recorded. We then adjust the rebate accruals as more information becomes available and to reflect actual claims experience. Estimating such rebates is complicated, in part because of the time delay between the date of sale and the actual settlement of the liability. We believe the

methodology we use to accrue for rebates is reasonable and appropriate given current facts and circumstances, but actual results may differ.

Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When healthcare providers purchase our products through wholesalers at these reduced prices, wholesalers charge us for the difference between their purchase prices and the contractual prices between Amgen and the healthcare providers. The provision for chargebacks is based on the expected sales by our wholesaler customers to healthcare providers. Accruals for wholesaler chargebacks are less difficult to estimate than rebates are, and they closely approximate actual results since chargeback amounts are fixed at the date of purchase by the healthcare providers and because we generally settle the liability for these deductions within a few weeks.

Product returns

Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. In each of the past three years, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-year sales return provisions have historically been immaterial.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is measured based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We believe our estimates for uncertain tax positions are appropriate and sufficient for any assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense.

Certain items are included in our tax return at different times than they are reflected in the financial statements and cause temporary differences between the tax bases of assets and liabilities and their reported amounts. Such temporary differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as a tax deduction or credit in the tax return in future years but for which we have already recorded the tax benefit in the consolidated financial statements. We establish valuation allowances against our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either: (i) tax expenses recognized in the consolidated financial statements for which payment has been deferred; (ii) expenses for which we have already taken a deduction on the tax return, but have not yet recognized the expense in the consolidated financial statements; or (iii) liabilities for the difference between the book basis and tax basis of the intangible assets acquired in many business combinations, as future expenses associated with these assets most often will not be tax deductible.

We are a vertically integrated enterprise with operations in the United States and various foreign jurisdictions. We are subject to income tax in the foreign jurisdictions where we conduct activities based on the tax laws and principles of such jurisdictions and the functions, risks and activities performed therein. Our pretax income is therefore attributed to domestic or foreign sources based on the operations performed and risks assumed in each location and the tax laws and principles of the respective taxing jurisdictions. For example, we conduct significant operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes, pertaining to manufacturing, distribution and other related functions to meet our worldwide product demand. Income from our operations in Puerto Rico is subject to tax incentive grants through 2035.

On December 22, 2017, the United States enacted the 2017 Tax Act, which imposes a repatriation tax on accumulated earnings of foreign subsidiaries, imposes a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. In December 2017, the SEC staff issued SAB 118, which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We have completed our

accounting for the tax effects of the 2017 Tax Act, including the repatriation tax, the net deferred tax remeasurement and the impact on our unrealized tax benefits. None of the adjustments we made to our provisional amounts were material to our consolidated financial statements.

As previously disclosed, we received a RAR from the IRS for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the

complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. See Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, U.S. state jurisdictions and other countries, including the U.S. territory of Puerto Rico, in which we do business. Significant changes in these rules could have a material adverse effect on our results of operations. See Part I, Item 1A. Risk Factors—The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters such as intellectual property disputes, contractual disputes and class action suits which are complex in nature and have outcomes that are difficult to predict. We describe our legal proceedings and other matters that are significant or that we believe could become significant in Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Valuation of assets and liabilities in connection with business combinations

We have acquired and continue to acquire intangible assets in connection with business combinations. These intangible assets consist primarily of technology associated with currently marketed human therapeutic products and IPR&D product candidates. Discounted cash flow models are typically used to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in a business combination. See Part IV—Note 3, Business combinations, to the Consolidated Financial Statements. These models require the use of significant estimates and assumptions, including, but not limited to:

- determining the timing and expected costs to complete in-process projects, taking into account the stage of completion at the acquisition date;
- projecting the probability and timing of obtaining marketing approval from the FDA and other regulatory agencies for product candidates;
- estimating the timing of and future net cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates to calculate the present values of the cash flows.

Significant estimates and assumptions are also required to determine the acquisition date fair values of any contingent consideration obligations incurred in connection with business combinations. In addition, we must revalue these obligations each subsequent reporting period until the related contingencies are resolved and record changes in their fair values in earnings. The acquisition date fair values of contingent consideration obligations incurred or assumed in the acquisitions of businesses were determined using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included, but were not limited to, the probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. These estimates and assumptions are required to be updated in order to revalue these contingent consideration obligations each reporting period. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these obligations.

We believe the fair values used to record intangible assets acquired and contingent consideration obligations incurred in connection with business combinations are based on reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Impairment of long-lived assets

We review the carrying value of our property, plant and equipment and our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows to be generated by the long-lived asset is compared to the

carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value.

Indefinite-lived intangible assets, composed of IPR&D projects acquired in a business combination that have not reached technological feasibility or that lack regulatory approval at the time of acquisition, are reviewed for impairment annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon establishment of technological feasibility or regulatory approval. We determine impairment by comparing the fair value of the asset to its carrying value. If the asset's carrying value exceeds its fair value, an impairment charge is recorded for the difference and its carrying value is reduced accordingly.

Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined, as described above. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations.

We believe our estimations of future cash flows used for assessing impairment of long-lived assets are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Recently Issued Accounting Standards

See Part IV—Note 1, Summary of significant accounting policies, to the Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of December 31, 2018.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in interest rates, foreign currency exchange rates and prices of equity instruments as well as changes in general economic conditions in the countries where we conduct business. To reduce certain of these risks, we enter into various types of foreign currency and interest rate derivative hedging transactions as part of our risk management program. We do not use derivatives for speculative trading purposes.

In the discussion that follows, we have assumed a hypothetical change in interest rates of 100 basis points from those as of December 31, 2018 and 2017. We have also assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2018 and 2017.

Interest-rate-sensitive financial instruments

Our portfolio of available-for-sale interest-bearing securities as of December 31, 2018 and 2017, was composed of U.S. Treasury securities and other government-related debt securities, corporate debt securities, residential mortgage-backed and other mortgage- and asset-backed securities, money market mutual funds and other short-term interest-bearing securities composed principally of commercial paper. The fair values of our investment portfolio of interest-bearing securities were $28.7 billion and $41.2 billion as of December 31, 2018 and 2017, respectively.

Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates as of December 31, 2018 and 2017, would have resulted in reductions in the fair values of these securities of $360 million and $1.1 billion, respectively, on these dates. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2018 and 2017, would not result in a material effect on income in the respective ensuing year.

As of December 31, 2018, we had outstanding debt with a carrying value of $33.9 billion and a fair value of $35.0 billion. As of December 31, 2017, we had outstanding debt with a carrying value of $35.3 billion and a fair value of $38.6 billion. Our outstanding debt was composed primarily of debt with fixed interest rates, with variable-rate debt having carrying values of $850 million as of December 31, 2018 and 2017. Changes in interest rates do not affect interest expense on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt.

A hypothetical 100 basis point decrease in interest rates relative to interest rates as of December 31, 2018 and 2017, would have resulted in increases of $2.6 billion and $3.3 billion, respectively, in the aggregate fair value of our outstanding debt on each of these dates. Analysis of the debt does not consider the impact that hypothetical changes in interest rates would have on the related interest rate swap contracts and cross-currency swap contracts, discussed below.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified and were designated for accounting purposes as fair value hedges for certain of our fixed-rate debt. These interest rate swap contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective note. Interest rate swap contracts with aggregate notional amounts of $10.95 billion and $9.45 billion were outstanding as of December 31, 2018 and 2017, respectively. A hypothetical 100 basis point increase in interest rates relative to interest rates as of December 31, 2018 and 2017, would have resulted in reductions in fair values of $460 million and $420 million, respectively, on our interest rate swap contracts on these dates and would not result in a material effect on the related income in the respective ensuing years. Analysis of the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest-rate-sensitive instruments were designed to offset.

As of December 31, 2018 and 2017, we had outstanding cross-currency swap contracts with aggregate notional amounts of $5.6 billion that hedge certain of our foreign-currency-denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros, pounds sterling and Swiss francs and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of December 31, 2018 and 2017, would have resulted in reductions in the fair values of our cross-currency swap contracts of $320 million and $390 million, respectively.

Foreign-currency-sensitive financial instruments

Our international operations are affected by fluctuations in the value of the U.S. dollar as compared to foreign currencies, predominantly the euro. Increases and decreases in our international product sales from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our international operating expenses. Increases and decreases in our foreign-currency-denominated assets from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our foreign-currency-denominated liabilities. To further reduce our net exposure to foreign currency exchange rate fluctuations on our results of operations, we enter into foreign currency forward, option and cross-currency swap contracts.

As of December 31, 2018, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and fair value of $5.3 billion and $5.6 billion, respectively. As of December 31, 2017, we had outstanding euro-, pound-sterling- and Swiss-franc-denominated debt with a principal carrying value and fair value of $6.2 billion and $6.7 billion, respectively. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2018, would have resulted in an increase in fair value of this debt of $1.1 billion on this date and a reduction in income in the ensuing year of $1.1 billion. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2017, would have resulted in an increase in fair value of this debt of $1.3 billion on this date and a reduction in income in the ensuing year of $1.2 billion. The impact on income from these hypothetical changes in foreign currency exchange rates would be substantially offset by the impact such changes would have on related cross-currency swap contracts, which are in place for the related foreign-currency-denominated debt.

We have cross-currency swap contracts that are designated as cash flow hedges of certain of our debt denominated in euros, pounds sterling and Swiss francs with an aggregate notional amount of $5.6 billion, as of December 31, 2018 and 2017. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would have resulted in reductions in the fair values of these contracts of $1.2 billion and $1.3 billion on these dates, respectively. The impact of this hypothetical adverse movement in foreign currency exchange rates on ensuing years' income from these contracts would be fully offset by the corresponding hypothetical changes in the carrying amounts of the related hedged debt.

We enter into foreign currency forward and options contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2018, we had open foreign currency forward and option contracts, primarily euro based with notional amounts of $4.5 billion and $21 million, respectively. As of December 31, 2017, we had open foreign currency forward and option contracts, primarily euro based with notional amounts of $4.6 billion and $74 million, respectively. As of December 31, 2018 the fair values of

these contracts were a $181 million asset and a $26 million liability. As of December 31, 2017 the fair values of these contracts were a $6 million asset and a $204 million liability. With regard to foreign currency forward and option contracts that were open as of December 31, 2018, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2018, would have resulted in a reduction in fair value of these contracts of $810 million on this date and, in the ensuing year, a reduction in income of $380 million. With regard to contracts that were open as of December 31, 2017, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2017, would have resulted in a reduction in fair value of these contracts of $930 million on this date and, in the ensuing year, a reduction in income of $360 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign-currency-sensitive instruments were designed to offset.

As of December 31, 2018 and 2017, we had open foreign currency forward contracts with notional amounts of $737 million and $757 million, respectively, that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2018 and 2017. With regard to these foreign currency forward contracts that were open as of December 31, 2018 and 2017, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have a material effect on the fair values of these contracts or related income in the respective ensuing years. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign-currency-sensitive instruments were designed to offset.

Market-price-sensitive financial instruments

As of December 31, 2018 and 2017, we were also exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments are generally in small-capitalization stocks in the biotechnology industry sector. Price risk relative to our equity investment portfolio as of December 31, 2018 and 2017, was not material.

Counterparty credit risks

Our financial instruments, including derivatives, are subject to counterparty credit risk, which we consider as part of the overall fair value measurement. Our financial risk management policy limits derivative transactions by requiring transactions to be with institutions with minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch and requires placing exposure limits on the amount with any individual counterparty. In addition, we have an investment policy that limits investments to certain types of debt and money market instruments issued by institutions primarily with investment-grade credit ratings and places restriction on maturities and concentrations by asset class and issuer.

## Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15(a)1 and (a)2 of Part IV and included in this Annual Report on Form 10-K.

## Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under the Securities Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2018.

Management determined that, as of December 31, 2018, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management’s Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company’s internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of the Company’s internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

The effectiveness of the Company’s internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting as of December 31, 2018.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Amgen Inc.

Opinion on Internal Control over Financial Reporting

We have audited Amgen Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amgen Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Amgen Inc. as of December 31, 2018 and 2017, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 and our report dated February 13, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Los Angeles, California

February 13, 2019

Item 9B. OTHER INFORMATION

Not applicable.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors is incorporated by reference from the section entitled ITEM 1—ELECTION OF DIRECTORS in our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2018 (the Proxy Statement). Information about compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference from the section entitled OTHER MATTERS—Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement. Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from APPENDIX A—AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS and OTHER MATTERS—Stockholder Proposals for the 2020 Annual Meeting in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE—Audit Committee in our Proxy Statement. Information about our executive officers is contained in the discussion entitled Part I—Item 1. Business—Executive Officers of the Registrant.

Code of Ethics

We maintain a Code of Ethics for the Chief Executive Officer and Senior Financial Officers applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, and other persons performing similar functions. To view this code of ethics free of charge, please visit our website at www.amgen.com. (This website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing.) We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics, if any, by posting such information on our website as set forth above.

Item 11. EXECUTIVE COMPENSATION

Information about director and executive compensation is incorporated by reference from the section entitled EXECUTIVE COMPENSATION in our Proxy Statement. Information about compensation committee matters is incorporated by reference from the sections entitled CORPORATE GOVERNANCE—Compensation and Management Development Committee and CORPORATE GOVERNANCE—Compensation Committee Report in our Proxy Statement.

## Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2018, concerning the shares of our common stock that may be issued under any form of award granted under our equity compensation plans in effect as of December 31, 2018 (including upon the exercise of options, the vesting of awards of restricted stock units (RSUs), or when performance units are earned, and related dividend equivalents have been granted).

| | (a) | (b) | (c) |
|---|---|---|---|
| Plan category | Number of securities to be issued upon exercise of outstanding options and rights | Weighted-average exercise price of outstanding options and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
| Equity compensation plans approved by Amgen security holders: | | | |
| Amended and Restated 2009 Equity Incentive Plan[1] | 9,900,975 | $ 143.61 | 32,159,877 |
| Amended and Restated 1991 Equity Incentive Plan[2] | 17,030 | — | — |
| Amended and Restated Employee Stock Purchase Plan | — | — | 4,634,563 |
| Total approved plans | 9,918,005 | 143.61 | 36,794,440 |
| Equity compensation plan not approved by Amgen security holders: | | | |
| Amgen Profit Sharing Plan for Employees in Ireland[3] | — | — | 95,087 |
| Total unapproved plans | — | — | 95,087 |
| Total all plans | 9,918,005 | $ 143.61 | 36,889,527 |

(1) The Amended and Restated 2009 Equity Incentive Plan employs a fungible share counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option or stock appreciation right counts as one share, while each restricted stock unit, performance unit or dividend equivalent counts as 1.9 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the fungible share counting formula. The number under column (c) represents the number of shares available for issuance under this plan based on each such available share counting as one share. Commencing with the grants made in April 2012, RSUs and performance units accrue dividend equivalents that are payable in shares only to the extent and when the underlying RSUs vest or underlying performance units have been earned and the related shares are issued to the grantee. The performance units granted under this plan are earned based on the accomplishment of specified performance goals at the end of their respective three-year performance periods; the number of performance units granted represent target performance and the maximum number of units that could be earned based on our performance is 200% of the performance units granted in 2016, 2017 and 2018.

As of December 31, 2018, the number of outstanding awards under column (a) includes: (i) 4,412,073 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of $143.61; (ii) 3,365,817 shares issuable upon the vesting of outstanding RSUs (including 172,613 related dividend equivalents); and (iii) 2,123,085 shares subject to outstanding 2016, 2017 and 2018 performance units (including 94,881 related dividend equivalents). The weighted-average exercise price shown in column (b) is for the outstanding options only. The number of available

shares under column (c) represents the number of shares that remain available for future issuance under this plan as of December 31, 2018, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2016, 2017 and 2018 and related dividend equivalents. The numbers under columns (a) and (c) do not give effect to the additional shares that could be issuable in the event above target on the performance goals under these outstanding performance units are achieved. Maximum performance under these goals could result in 200% of target shares being awarded for performance units granted in 2016, 2017 and 2018.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 17,030 shares issuable upon the settlement of deferred RSUs (including 2,577 related dividend equivalents).

(3) The Amgen Profit Sharing Plan for Employees in Ireland (the Profit Sharing Plan) was approved by the Board of Directors on July 28, 2011. The Profit Sharing Plan permits eligible employees of the Company's subsidiaries located in Ireland who participate in the Profit Sharing Plan to apply a portion of their qualifying bonus and salary to the purchase the Company's common stock on the open market at the market price by a third-party trustee as described in the Profit Sharing Plan.

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

Information about security ownership of certain beneficial owners and management is incorporated by reference from the sections entitled SECURITY OWNERSHIP OF DIRECTORS AND EXECUTIVE OFFICERS and SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS in our Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information about certain relationships and related transactions and director independence is incorporated by reference from the sections entitled CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS and CORPORATE GOVERNANCE—Director Independence in our Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information about the fees for professional services rendered by our independent registered public accountants is incorporated by reference from the section entitled AUDIT MATTERS—Independent Registered Public Accountants in our Proxy Statement.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:


| | Page number |
|---|---|
| Report of Independent Registered Public Accounting Firm | F-1 |
| Consolidated Statements of Income for each of the three years in the period ended December 31, 2018 | F-2 |
| Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2018 | F-3 |
| Consolidated Balance Sheets as of December 31, 2018 and 2017 | F-4 |
| Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2018 | F-5 |
| Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2018 | F-6 |
| Notes to Consolidated Financial Statements | F-7 |


(a)2. Index to Financial Statement Schedules

The following Schedule is filed as part of this Annual Report on Form 10-K:


| | Page number |
|---|---|
| II. Valuation and Qualifying Accounts | F-53 |


All other schedules are omitted because they are not applicable, not required or because the required information is included in the consolidated financial statements or notes thereto.

(a)3. Exhibits

| Exhibit No. | Description |
|---|---|
| 3.1 | Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.) |
| 3.2 | Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.) |
| 4.1 | Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.) |
| 4.2 | Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.) |
| 4.3 | Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.) |
| 4.4 | First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.) |

| | |
|---|---|
| 4.5 | 8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.) |
| 4.6 | Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.) |

| | |
|---|---|
| 4.7 | Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.) |
| 4.8 | Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.) |
| 4.9 | Officers' Certificate of Amgen Inc., dated May 30, 2007, including forms of the Company's Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.) |
| 4.10 | Officers' Certificate of Amgen Inc., dated May 23, 2008, including forms of the Company's 6.15% Senior Notes due 2018 and 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.) |
| 4.11 | Officers' Certificate of Amgen Inc., dated January 16, 2009, including forms of the Company's 5.70% Senior Notes due 2019 and 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.) |
| 4.12 | Officers' Certificate of Amgen Inc., dated March 12, 2010, including forms of the Company's 4.50% Senior Notes due 2020 and 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.) |
| 4.13 | Officers' Certificate of Amgen Inc., dated September 16, 2010, including forms of the Company's 3.45% Senior Notes due 2020 and 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.) |
| 4.14 | Officers' Certificate of Amgen Inc., dated June 30, 2011, including forms of the Company's 2.30% Senior Notes due 2016, 4.10% Senior Notes due 2021 and 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.) |
| 4.15 | Officers' Certificate of Amgen Inc., dated November 10, 2011, including forms of the Company's 1.875% Senior Notes due 2014, 2.50% Senior Notes due 2016, 3.875% Senior Notes due 2021 and 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.) |
| 4.16 | Officers' Certificate of Amgen Inc., dated December 5, 2011, including forms of the Company's 4.375% Senior Notes due 2018 and 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.) |
| 4.17 | Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 2.125% Senior Notes due 2017, 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.) |
| 4.18 | Officers' Certificate of Amgen Inc., dated September 13, 2012, including forms of the Company's 2.125% Senior Notes due 2019 and 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.) |
| 4.19 | Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.) |

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| 4.20 | Officers' Certificate of Amgen Inc., dated May 22, 2014, including forms of the Company's Senior Floating Rate Notes due 2017, Senior Floating Rate Notes due 2019, 1.250% Senior Notes due 2017, 2.200% Senior Notes due 2019 and 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.) |
| 4.21 | Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 2.125% Senior Notes due 2020, 2.700% Senior Notes due 2022, 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.) |
| 4.22 | Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.) |
| 4.23 | Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.) |
| 4.24 | Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.) |

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| 4.25 | Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.) |
| 4.26 | Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 1.850% Senior Notes due 2021, 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.) |
| 4.27 | Officer's Certificate of Amgen Inc., dated as of May 11, 2017 including forms of the Company's Senior Floating Rate Notes due 2019, Senior Floating Rate Notes due 2020, 1.900% Senior Notes due 2019, 2.200% Senior Notes due 2020 and 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated herein by reference.) |
| 4.28 | Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated by reference.) |
| 10.1+ | Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.) |
| 10.2+ | First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.) |
| 10.3+ | Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.) |
| 10.4+* | Form of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 7, 2018.) |
| 10.5+* | Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 7, 2018.) |
| 10.6+ | Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.) |
| 10.7+* | Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 7, 2018.) |
| 10.8+ | Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on October 24, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.) |
| 10.9+ | Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.) |
| 10.10+ | |

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| | Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on October 24, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.) |
| 10.11+ | Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.) |
| 10.12+ | Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.) |
| 10.13+ | First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.) |
| 10.14+ | Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.) |
| 10.15+ | Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.) |

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| 10.16+ | First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.) |
| 10.17+ | Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.) |
| 10.18+ | Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.) |
| 10.19+ | First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.) |
| 10.20+ | Agreement between Amgen Inc. and David W. Meline, effective July 21, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2014 on October 29, 2014 and incorporated herein by reference.) |
| 10.21+ | Agreement between Amgen Inc. and Jonathan Graham, dated May 11, 2015. (Filed as an exhibit to Form 10-Q/A for the quarter ended June 30, 2015 on August 6, 2015 and incorporated herein by reference.) |
| 10.22+ | Agreement between Amgen Inc. and Lori Johnston, dated October 25, 2016. (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.) |
| 10.23+ | Agreement between Amgen Inc. and Murdo Gordon, dated July 25, 2018. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2018 on October 31, 2018 and incorporated herein by reference.) |
| 10.24 | Amended and Restated Credit Agreement, dated July 30, 2014, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent (the "Credit Agreement"). (Filed as an exhibit to Form 8-K on July 30, 2014 and incorporated herein by reference.) |
| 10.25 | Amendment No. 1 to the Credit Agreement, dated March 9, 2018, among Amgen Inc., the Banks therein named, and Citibank, N.A., as administrative agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.) |
| 10.26 | Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.) |
| 10.27 | Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.) |
| 10.28 | |

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| | Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.) |
| 10.29 | Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.) |
| 10.30 | Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.) |
| 10.31 | Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.) |
| 10.32 | Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.) |

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| 10.33 | Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.) |
| 10.34 | Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.) |
| 10.35 | Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.) |
| 10.36 | Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.) |
| 10.37 | Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.) |
| 10.38 | Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.) |
| 10.39 | Amendment No. 1 to the Collaboration Agreement, dated March 20, 2018, by and between Novartis Pharma AG and Amgen Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2018 on April 25, 2018 and incorporated herein by reference.) |
| 21* | Subsidiaries of the Company |
| 23 | Consent of the Independent Registered Public Accounting Firm. The consent is set forth on page 74 of this Annual Report on the 10-K. |
| 24 | Power of Attorney. The Power of Attorney is set forth on page 75 of this Annual Report on Form 10-K. |
| 31* | Rule 13a-14(a) Certifications. |
| 32** | Section 1350 Certifications. |
| 101.INS* | XBRL Instance Document. |
| 101.SCH* | XBRL Taxonomy Extension Schema Document. |

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB* XBRL Taxonomy Extension Label Linkbase Document.

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document.

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(* = filed herewith)
(** = furnished herewith and not “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended)
(+ = management contract or compensatory plan or arrangement)
Item 16. FORM 10-K SUMMARY
Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: February 13, 2019 By: /S/ DAVID W. MELINE
David W. Meline
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-8 No. 333-159377) pertaining to the Amgen Inc. 2009 Equity Incentive Plan;
- Registration Statement (Form S-8 No. 33-39183) pertaining to the Amended and Restated Employee Stock Purchase Plan;
- Registration Statements (Form S-8 No. 33-39104, as amended by Form S-8 Nos. 333-144581 and 333-216719) pertaining to the Amended and Restated Amgen Retirement and Savings Plan (formerly known as the Amgen Retirement and Savings Plan);
- Registration Statements (Form S-8 Nos. 33-47605, 333-144580 and 333-216715) pertaining to the Retirement and Savings Plan for Amgen Manufacturing, Limited (formerly known as the Retirement and Savings Plan for Amgen Manufacturing, Inc.);
- Registration Statements (Form S-8 Nos. 333-81284, 333-177868 and 333-216723) pertaining to the Amgen Nonqualified Deferred Compensation Plan;
- Registration Statement (Form S-3 No. 333-216060) relating to debt securities, common stock, preferred stock, warrants to purchase debt securities, common stock, preferred stock or depositary shares, rights to purchase common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares of Amgen Inc. and in the related Prospectus; and
- Registration Statement (Form S-8 No. 333-176240) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland;

of our reports dated February 13, 2019, with respect to the consolidated financial statements of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Los Angeles, California

February 13, 2019

EXHIBIT 24
POWER OF ATTORNEY
KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David W. Meline, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming that said attorney-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.
Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

| Signature | Title | Date |
|---|---|---|
| /S/ ROBERT A. BRADWAY<br>Robert A. Bradway | Chairman of the Board, Chief Executive Officer and President, and Director<br>(Principal Executive Officer) | 2/13/2019 |
| /S/ DAVID W. MELINE<br>David W. Meline | Executive Vice President and Chief Financial Officer<br>(Principal Financial and Accounting Officer) | 2/13/2019 |
| /S/ WANDA M. AUSTIN<br>Wanda M. Austin | Director | 2/13/2019 |
| /S/ BRIAN J. DRUKER<br>Brian J. Druker | Director | 2/13/2019 |
| /S/ ROBERT A. ECKERT<br>Robert A. Eckert | Director | 2/13/2019 |
| /S/ GREG C. GARLAND<br>Greg C. Garland | Director | 2/13/2019 |
| /S/ FRED HASSAN<br>Fred Hassan | Director | 2/13/2019 |
| /S/ REBECCA M. HENDERSON<br>Rebecca M. Henderson | Director | 2/13/2019 |
| /S/ FRANK C. HERRINGER<br>Frank C. Herringer | Director | 2/13/2019 |
| /S/ CHARLES M. HOLLEY, JR.<br>Charles M. Holley, Jr. | Director | 2/13/2019 |
| /S/ TYLER JACKS<br>Tyler Jacks | Director | 2/13/2019 |
| /S/ ELLEN J. KULLMAN<br>Ellen J. Kullman | Director | 2/13/2019 |

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| /S/ RONALD D. SUGAR<br>Ronald D. Sugar | Director | 2/13/2019 |
| /S/ R. SANDERS WILLIAMS<br>R. Sanders Williams | Director | 2/13/2019 |

Report of Independent Registered Public Accounting Firm
To the Board of Directors and Stockholders of Amgen Inc.
Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amgen Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.
We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 13, 2019 expressed an unqualified opinion thereon.
Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.
/s/ Ernst & Young LLP
We have served as the Company's auditor since 1980.
Los Angeles, California
February 13, 2019

AMGEN INC.
CONSOLIDATED STATEMENTS OF INCOME
Years ended December 31, 2018, 2017 and 2016
(In millions, except per-share data)

| | 2018 | 2017 | 2016 |
|---|---|---|---|
| Revenues: | | | |
| Product sales | $22,533 | $21,795 | $21,892 |
| Other revenues | 1,214 | 1,054 | 1,099 |
| Total revenues | 23,747 | 22,849 | 22,991 |
| | | | |
| Operating expenses: | | | |
| Cost of sales | 4,101 | 4,069 | 4,162 |
| Research and development | 3,737 | 3,562 | 3,840 |
| Selling, general and administrative | 5,332 | 4,870 | 5,062 |
| Other | 314 | 375 | 133 |
| Total operating expenses | 13,484 | 12,876 | 13,197 |
| | | | |
| Operating income | 10,263 | 9,973 | 9,794 |
| | | | |
| Interest expense, net | 1,392 | 1,304 | 1,260 |
| Interest and other income, net | 674 | 928 | 629 |
| | | | |
| Income before income taxes | 9,545 | 9,597 | 9,163 |
| | | | |
| Provision for income taxes | 1,151 | 7,618 | 1,441 |
| | | | |
| Net income | $8,394 | $1,979 | $7,722 |
| | | | |
| Earnings per share: | | | |
| Basic | $12.70 | $2.71 | $10.32 |
| Diluted | $12.62 | $2.69 | $10.24 |
| | | | |
| Shares used in the calculation of earnings per share: | | | |
| Basic | 661 | 731 | 748 |
| Diluted | 665 | 735 | 754 |

See accompanying notes.

AMGEN INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
Years ended December 31, 2018, 2017 and 2016
(In millions)

| | 2018 | 2017 | 2016 |
|---|---|---|---|
| Net income | $8,394 | $1,979 | $7,722 |
| Other comprehensive (loss) income, net of reclassification adjustments and taxes: | | | |
| (Losses) gains on foreign currency translation | (141) | 81 | (99) |
| Gains (losses) on cash flow hedges | 247 | (288) | (15) |
| (Losses) gains on available-for-sale securities | (185) | (6) | 122 |
| Other | (2) | 5 | 1 |
| Other comprehensive (loss) income, net of tax | (81) | (208) | 9 |
| Comprehensive income | $8,313 | $1,771 | $7,731 |

See accompanying notes.

AMGEN INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2018 and 2017
(In millions, except per-share data)

| | 2018 | 2017 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $6,945 | $3,800 |
| Marketable securities | 22,359 | 37,878 |
| Trade receivables, net | 3,580 | 3,237 |
| Inventories | 2,940 | 2,834 |
| Other current assets | 1,794 | 1,727 |
| Total current assets | 37,618 | 49,476 |
| Property, plant and equipment, net | 4,958 | 4,989 |
| Intangible assets, net | 7,443 | 8,609 |
| Goodwill | 14,699 | 14,761 |
| Other assets | 1,698 | 2,119 |
| Total assets | $66,416 | $79,954 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $1,207 | $1,352 |
| Accrued liabilities | 7,862 | 6,516 |
| Current portion of long-term debt | 4,419 | 1,152 |
| Total current liabilities | 13,488 | 9,020 |
| Long-term debt | 29,510 | 34,190 |
| Long-term deferred tax liabilities | 864 | 1,166 |
| Long-term tax liabilities | 8,770 | 9,099 |
| Other noncurrent liabilities | 1,284 | 1,238 |
| Contingencies and commitments | | |
| Stockholders' equity: | | |
| Common stock and additional paid-in capital; $0.0001 par value per share; 2,750.0 shares authorized; outstanding—629.6 shares in 2018 and 722.2 shares in 2017 | 31,246 | 30,992 |
| Accumulated deficit | (17,977) | (5,072) |
| Accumulated other comprehensive loss | (769) | (679) |
| Total stockholders' equity | 12,500 | 25,241 |
| Total liabilities and stockholders' equity | $66,416 | $79,954 |

See accompanying notes.

AMGEN INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years ended December 31, 2018, 2017 and 2016
(In millions)

| | Number of shares of common stock | Common stock and additional paid-in capital | Accumulated deficit | Accumulated other comprehensive loss | Total |
|---|---|---|---|---|---|
| Balance as of December 31, 2015 | 754.0 | $ 30,649 | $ (2,086) | $ (480) | $ 28,083 |
| Net income | — | — | 7,722 | — | 7,722 |
| Other comprehensive income, net of tax | — | — | — | 9 | 9 |
| Dividends declared on common stock ($4.15 per share) | — | — | (3,120) | — | (3,120) |
| Issuance of common stock in connection with the Company's equity award programs | 3.9 | 55 | — | — | 55 |
| Stock-based compensation expense | — | 342 | — | — | 342 |
| Tax impact related to employee stock-based compensation expense | — | (262) | 73 | — | (189) |
| Repurchases of common stock | (19.7) | — | (3,027) | — | (3,027) |
| Balance as of December 31, 2016 | 738.2 | 30,784 | (438) | (471) | 29,875 |
| Net income | — | — | 1,979 | — | 1,979 |
| Other comprehensive loss, net of tax | — | — | — | (208) | (208) |
| Dividends declared on common stock ($4.77 per share) | — | — | (3,487) | — | (3,487) |
| Issuance of common stock in connection with the Company's equity award programs | 2.5 | 52 | — | — | 52 |
| Stock-based compensation expense | — | 347 | — | — | 347 |
| Tax impact related to employee stock-based compensation expense | — | (191) | — | — | (191) |
| Repurchases of common stock | (18.5) | — | (3,126) | — | (3,126) |
| Balance as of December 31, 2017 | 722.2 | 30,992 | (5,072) | (679) | 25,241 |
| Cumulative effect of changes in accounting principles, net of tax | — | — | 38 | (9) | 29 |
| Net income | — | — | 8,394 | — | 8,394 |
| Other comprehensive loss, net of tax | — | — | — | (81) | (81) |
| Dividends declared on common stock ($5.41 per share) | — | — | (3,482) | — | (3,482) |
| Issuance of common stock in connection with the Company's equity award programs | 1.9 | 56 | — | — | 56 |
| Stock-based compensation expense | — | 327 | — | — | 327 |
| Tax impact related to employee stock-based compensation expense | — | (129) | — | — | (129) |
| Repurchases of common stock | (94.5) | — | (17,855) | — | (17,855) |
| Balance as of December 31, 2018 | 629.6 | $ 31,246 | $ (17,977) | $ (769) | $ 12,500 |

See accompanying notes.

AMGEN INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2018, 2017 and 2016
(In millions)

| | 2018 | 2017 | 2016 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net income | $8,394 | $1,979 | $7,722 |
| Depreciation and amortization | 1,946 | 1,955 | 2,105 |
| Stock-based compensation expense | 311 | 329 | 311 |
| Deferred income taxes | (363) | (1,330) | 183 |
| Other items, net | 386 | 334 | 32 |
| Changes in operating assets and liabilities, net of acquisitions: | | | |
| Trade receivables, net | (378) | (58) | (214) |
| Inventories | (3) | 133 | (80) |
| Other assets | 35 | (24) | (128) |
| Accounts payable | (143) | 424 | (44) |
| Accrued income taxes, net | (361) | 523 | (301) |
| Long-term tax liabilities | 258 | 6,681 | 445 |
| Other liabilities | 1,214 | 231 | 323 |
| Net cash provided by operating activities | 11,296 | 11,177 | 10,354 |
| Cash flows from investing activities: | | | |
| Purchases of marketable securities | (18,741) | (33,607) | (28,094) |
| Proceeds from sales of marketable securities | 28,356 | 24,240 | 17,958 |
| Proceeds from maturities of marketable securities | 5,412 | 6,174 | 2,459 |
| Purchases of property, plant and equipment | (738) | (664) | (738) |
| Cash acquired in acquisition, net of cash paid | 195 | (19) | — |
| Other | (145) | (148) | (243) |
| Net cash provided by (used in) investing activities | 14,339 | (4,024) | (8,658) |
| Cash flows from financing activities: | | | |
| Net proceeds from issuance of debt | — | 4,476 | 7,318 |
| Repayment of debt | (1,121) | (4,405) | (3,725) |
| Repurchases of common stock | (17,794) | (3,160) | (2,965) |
| Dividends paid | (3,507) | (3,365) | (2,998) |
| Withholding taxes arising from shares withheld for share-based payments | (126) | (191) | (260) |
| Other | 58 | 51 | 31 |
| Net cash used in financing activities | (22,490) | (6,594) | (2,599) |
| Increase (decrease) in cash and cash equivalents | 3,145 | 559 | (903) |
| Cash and cash equivalents at beginning of year | 3,800 | 3,241 | 4,144 |
| Cash and cash equivalents at end of year | $6,945 | $3,800 | $3,241 |

See accompanying notes.

AMGEN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2018

1. Summary of significant accounting policies

Business

Amgen Inc. (including its subsidiaries, referred to as “Amgen,” “the Company,” “we,” “our” or “us”) is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. We operate in one business segment: human therapeutics.

Principles of consolidation

The consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. We do not have any significant interests in any variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Revenues

Adoption of new revenue recognition standard

In May 2014, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards require an entity to recognize revenue when control of promised goods or services is transferred to the customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted this new standard as of January 1, 2018, by applying the modified-retrospective method to those contracts that were not completed as of that date.

The results for reporting periods beginning after January 1, 2018, are presented in accordance with the new standard, although comparative information has not been restated and continues to be reported under the accounting standards and policies in effect for those periods.

Upon adoption, we recorded a net decrease of $25 million to Accumulated deficit due to the cumulative impact of adopting the new standard—with the impact related primarily to the acceleration of deferred revenue, net of related deferred tax impact. The adoption of this new standard had an immaterial impact on our reported total revenues and operating income as compared to what reported amounts would have been under the prior standard, and we expect the impact of adoption in future periods to also be immaterial. Our accounting policies under the new standard were applied prospectively and are described below. See Note 4, Revenues.

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that an adjustment is appropriate. Accruals are also adjusted to reflect actual results. Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given period, can be affected by the mix of products sold. Included in sales deductions are immaterial net adjustments related to prior-period sales due to changes in estimates. Historically, such amounts have represented less than 1% of the aggregate sales deductions charged against product sales.

Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. Historically, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-period sales return provisions have historically been immaterial.

Our payment terms vary by types and locations of customers and the products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 120 days from date of shipment or satisfaction of the performance obligation. For certain products or services and certain customer types, we may require payment before products are delivered or services are rendered to customers.

Indirect taxes collected from customers and remitted to government authorities and that are related to sales of the Company's products, primarily in Europe, are excluded from revenues.

As a practical expedient, sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in Selling, general and administrative expense in the Consolidated Statements of Income.

Other revenues

Other revenues consist primarily of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Royalty estimates are based on historical and forecasted sales trends. Corporate partner revenues are composed mainly of license fees and milestones earned and our share of commercial profits generated from collaborations. See Arrangements with multiple-performance obligations, discussed below.

Arrangements with multiple-performance obligations

From time to time, we enter into arrangements for the research and development (R&D), manufacture and/or commercialization of products and product candidates. Such arrangements may require us to deliver various rights, services and/or goods, including intellectual property rights/licenses, R&D services, manufacturing services and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to Amgen in the form of nonrefundable upfront license fees, development and commercial performance milestone payments, royalty payments and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. We utilize the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Research and development costs

R&D costs are expensed as incurred and include primarily salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs; and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with third-party R&D arrangements, including upfront fees and milestones paid to third parties in connection with technologies that had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 9, Collaborations.

Selling, general and administrative costs

Selling, general and administrative (SG&A) costs are composed primarily of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; the U.S. healthcare reform federal excise fee on Branded Prescription Pharmaceutical Manufacturers and Importers; and other general and administrative costs. Advertising costs are expensed as incurred and were $674 million, $620 million and $489 million during the years ended December 31, 2018, 2017 and 2016, respectively. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaborative

arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 9, Collaborations.

Stock-based compensation

We have stock-based compensation plans under which various types of equity-based awards are granted, including restricted stock units (RSUs), performance units and stock options. The fair values of RSUs and stock option awards, which are subject only to service conditions with graded vesting, are recognized as compensation expense, generally on a straight-line basis over the service period, net of estimated forfeitures. The fair values of performance unit awards are recognized as compensation expense, generally on a straight-line basis from the grant date to the end of the performance period. See Note 5, Stock-based compensation.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate. Significant judgment is required in determining our provision for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws. Deferred income taxes are recorded for the expected tax consequences of temporary differences between the bases of assets and liabilities, as well as for loss and tax credit carryforwards for financial reporting purposes and amounts recognized for income tax purposes. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (UTBs) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense. See Note 7, Income taxes.

Business combinations

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process research and development (IPR&D) projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination (including the assumption of an acquiree’s liability arising from a business combination it consummated prior to our acquisition) are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings. See Note 3, Business combinations, and Note 18, Fair value measurement.

Cash equivalents

We consider cash equivalents to be only those investments that are highly liquid, readily convertible to cash and which mature within three months from the date of purchase.

Interest-bearing securities

We consider our interest-bearing securities investment portfolio available-for-sale, and accordingly, these investments are recorded at fair value, with unrealized gains and losses recorded in Accumulated other comprehensive income (loss) (AOCI). Investments with maturities beyond one year may be classified as short-term marketable securities in the Consolidated Balance Sheets due to their highly liquid nature and because they represent the Company’s investments that are available for current operations. See Note 11, Investments, and Note 18, Fair value measurement.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. See Note 12, Inventories.

Derivatives

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. The accounting for changes in the fair value of a derivative instrument depends on whether the derivative has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of

hedging relationship. For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter, whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. See Note 18, Fair value measurement, and Note 19, Derivative instruments.

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation, amortization and, if applicable, impairment charges. We review our property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Depreciation is provided over the assets' useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 13, Property, plant and equipment.

Goodwill and other intangible assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 14, Goodwill and other intangible assets.

The fair values of IPR&D projects acquired in a business combination that are not complete are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market the resulting products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. We consider various factors for potential impairment, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays in obtaining marketing approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

We perform an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To date, an impairment of goodwill has not been recorded. See Note 14, Goodwill and other intangible assets.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Note 20, Contingencies and commitments. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Foreign currency translation

The net assets of international subsidiaries whose local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating net assets of these subsidiaries at changing rates are recognized in AOCI. The earnings of these subsidiaries are translated into U.S. dollars using average exchange rates.

Other recently adopted pronouncements

In January 2016, the FASB issued a new accounting standard that amends the accounting and disclosures of financial instruments, including a provision requiring that equity investments (except for investments accounted for under the equity method of accounting) be measured at fair value, with changes in fair value recognized in current earnings. With the exception of equity investments that were previously accounted for at cost, a modified-retrospective

approach was used to reflect the cumulative-effect of adoption as an adjustment to Accumulated deficit as of the beginning of the fiscal year. The new standard will be applied prospectively to investments currently that were previously accounted for at cost. Upon adoption, on January 1, 2018, we recorded

an immaterial adjustment to Accumulated deficit from AOCI, which represented the net unrealized gain on all equity investments with readily determinable fair values as of December 31, 2017. The impact that this new standard has on our consolidated statements of income after adoption will depend on changes in fair values of equity securities in our portfolio in the future. See Note 11, Investments.

In October 2016, the FASB issued a new accounting standard that amends the income tax accounting guidance for intra-entity transfers of assets other than inventory. The new standard requires that entities recognize the income tax consequences of an intercompany transfer of an asset, other than inventory, in the period the transfer occurs. The current exception to defer the recognition of any tax impact on intercompany transfers of inventory until the inventory is sold to a third party remains unaffected. We adopted this standard as of January 1, 2018, and will apply it to any transaction occurring on or after the adoption date. The adoption of this standard did not have a material impact on our consolidated financial statements; however, the impact on our consolidated financial statements in future periods will depend on the facts and circumstances of future transactions.

In January 2017, the FASB issued a new accounting standard that changes the definition of a business to assist entities with the evaluation of when a set of assets acquired or disposed of should be considered a business. The new standard requires that an entity evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets; if so, the set of assets would not be considered a business. The new standard also requires that a business include at least one substantive process, and it narrows the definition of outputs. We adopted this standard as of January 1, 2018. Adoption of this new standard may result in more transactions being accounted for as asset acquisitions versus business combinations; however, the impact on our consolidated financial statements in future periods will depend on the facts and circumstances of future transactions.

In August 2017, the FASB issued a new accounting standard that amends the accounting and reporting of hedging activities, which we elected to adopt early during the second quarter of 2018. Among its provisions, the new standard (i) eliminates the separate measurement and reporting of hedge ineffectiveness and (ii) permits an entity to recognize in earnings the initial fair value of an excluded component of a hedging instrument's fair value under a systematic and rational method over the life of the derivative instrument. In accordance with the transition provisions of the new standard, the separate measurement of ineffectiveness for our cash flow hedging instruments existing as of the date of adoption is required to be eliminated through a cumulative-effect adjustment to Accumulated deficit as of January 1, 2018, the beginning of the fiscal year. In addition, certain provisions in the guidance require modifications to existing presentation and disclosure requirements on a prospective basis. The adoption of this standard did not have a material impact on our consolidated financial statements. See Note 19, Derivative instruments.

Other recent accounting pronouncements

In February 2016, the FASB issued a new accounting standard that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize on the balance sheet the assets and liabilities that arise from leases, including leases classified as operating leases under current GAAP, and disclose qualitative and quantitative information about leasing arrangements. The new standard requires a modified-retrospective approach to adoption and is effective for interim and annual periods beginning on January 1, 2019. In July 2018, the FASB further amended this standard to allow for a new transition method that offers the option to use the effective date as the date of initial application. We intend to elect this alternative transition method and therefore will not adjust comparative-period financial information. In addition, we intend to elect the package of practical expedients permitted under the transition guidance of the new standard to not reassess prior conclusions related to contracts that are or that contain leases, lease classification and initial direct costs. We do not expect that this standard will have a material impact on our Consolidated Statements of Income. The primary effect of adoption will be the requirement to record the present value of lease liabilities for current operating leases and corresponding right-of-use (ROU) assets. Upon adoption, we estimate we will have additional liabilities ranging from $400 million to $450 million with corresponding ROU assets of a similar amount for lease agreements in effect as of December 31, 2018. The actual impact will depend on our lease portfolio at the time of adoption. We are currently finalizing the implementation of the lease accounting information system, documenting processes, and establishing internal controls to properly track, record and account for our lease portfolio. The new standard also provides practical expedients for the ongoing accounting. We also currently expect to elect the practical expedient to not separate lease and nonlease components

for most of our asset classes.

In June 2016, the FASB issued a new accounting standard that amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The new standard is effective for interim and annual periods beginning on January 1, 2020, but may be adopted earlier, beginning on January 1, 2019. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. We are currently evaluating the impact that this new standard will have on our consolidated financial statements.

2. Restructuring

In 2014, we initiated a restructuring plan to invest in continuing innovation and the launch of our new pipeline molecules, while improving our cost structure. As part of the plan, we closed facilities in Washington State and Colorado and are reducing the number of buildings we occupy at our headquarters in Thousand Oaks, California, as well as at other locations. We completed the activities associated with this restructuring plan in 2018.

Through December 31, 2018, we incurred $548 million of separation costs and other headcount-related costs for staff reductions and $261 million of net asset-related charges, which consist primarily of asset impairments, accelerated depreciation and other related costs resulting from the consolidation of our worldwide facilities. During the years ended December 31, 2018, 2017 and 2016, we incurred restructuring costs of $12 million, $88 million and $37 million, respectively. As of December 31, 2018 and 2017, the restructuring liabilities were not significant.

3. Business combinations

Kirin-Amgen, Inc.

During the first quarter of 2018, we acquired the remaining 50% ownership of Kirin-Amgen, Inc. (K-A), from Kirin Holdings Company, Limited (Kirin), making K-A a wholly owned subsidiary of Amgen. Upon its acquisition, K-A's operations have been included in our consolidated financial statements commencing on the share acquisition date. The acquisition relieved Amgen of future royalty obligations to K-A.

Prior to the share acquisition date, we owned 50% of K-A and accounted for our interest in K-A by using the equity method of accounting. See Note 10, Related party transactions.

The transaction was accounted for as a step acquisition of a business in which we were required to remeasure our existing 50% ownership interest at fair value. In addition, we were required to effectively settle our preexisting relationship with K-A, which resulted in a loss. Together the gain on the remeasurement of our existing ownership interest and the loss from the settlement of the preexisting relationship resulted in a net gain of $80 million, which was recorded in Interest and other income, net, in the Consolidated Statements of Income.

The primary means of consideration for this transaction was a payment of $780 million in cash. The aggregate share acquisition date consideration to acquire the remaining 50% ownership in K-A and the fair value of Amgen's preacquisition investment consisted of the following (in millions):

| | Amounts |
|---|---|
| Total cash paid to Kirin | $ 780 |
| Fair value of contingent consideration obligation | 45 |
| Loss on settlement of preexisting relationship | (168 ) |
| Total consideration transferred to acquire K-A | 657 |
| | |
| Fair value of Amgen's investment in K-A | 825 |
| Total acquisition date fair value | $ 1,482 |

In connection with this acquisition, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab. The estimated fair value of this contingent consideration obligation was $45 million as of the share acquisition date.

The fair values of assets acquired and liabilities assumed consisted of cash of $977 million, licensing rights of $470 million, deferred tax liabilities of $102 million, other assets and liabilities of $131 million and goodwill of $6 million. The estimated fair value of acquired licensing rights was determined by using a probability-weighted-income approach, which discounts expected future cash flows to present value by using a discount rate that represents the estimated rate that market participants would use to value the assets. The projected cash flows were based on certain assumptions, including estimates of future revenues and expenses and the time and resources needed to maintain the assets through commercialization. The licensing rights will be amortized over a weighted-average period of four years by using the straight-line method. The excess of the share acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $6 million was recorded as goodwill, which is not deductible for tax purposes. The $131 million in other assets and liabilities represents primarily receivables for royalties earned by K-A but not yet received, offset partially by payables representing R&D expenses incurred but not yet reimbursed by K-A.

Pro forma results of operations for this acquisition have not been presented because this acquisition is not material to our consolidated results of operations.

4. Revenues

We operate in one business segment: human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues by product and by geographic area, based on customers' locations, are presented below. Rest-of-world (ROW) revenues relate to products that are sold principally in Europe.

Revenues were as follows (in millions):

| | Year ended December 31, 2018 | | |
|---|---|---|---|
| | US | ROW | Total |
| Enbrel® (etanercept) | $4,807 | $207 | $5,014 |
| Neulasta® (pegfilgrastim) | 3,866 | 609 | 4,475 |
| Prolia® (denosumab) | 1,500 | 791 | 2,291 |
| Aranesp® (darbepoetin alfa) | 942 | 935 | 1,877 |
| XGEVA® (denosumab) | 1,338 | 448 | 1,786 |
| Sensipar® / Mimpara® (cinacalcet) | 1,436 | 338 | 1,774 |
| EPOGEN® (epoetin alfa) | 1,010 | — | 1,010 |
| Other products | 2,530 | 1,776 | 4,306 |
| Total product sales(1) | 17,429 | 5,104 | 22,533 |
| Other revenues | 929 | 285 | 1,214 |
| Total revenues(2) | $18,358 | $5,389 | $23,747 |

| | Year ended December 31, 2017 | | |
|---|---|---|---|
| | US | ROW | Total |
| ENBREL | $5,206 | $227 | $5,433 |
| Neulasta® | 3,931 | 603 | 4,534 |
| Aranesp® | 1,114 | 939 | 2,053 |
| Prolia® | 1,272 | 696 | 1,968 |
| Sensipar® / Mimpara® | 1,374 | 344 | 1,718 |
| XGEVA® | 1,157 | 418 | 1,575 |
| EPOGEN® | 1,096 | — | 1,096 |
| Other products | 1,981 | 1,437 | 3,418 |
| Total product sales[1] | 17,131 | 4,664 | 21,795 |
| Other revenues | 898 | 156 | 1,054 |
| Total revenues[2] | $18,029 | $4,820 | $22,849 |

| | Year ended December 31, 2016 | | |
|---|---|---|---|
| | US | ROW | Total |
| ENBREL | $5,719 | $246 | $5,965 |
| Neulasta® | 3,925 | 723 | 4,648 |
| Aranesp® | 1,082 | 1,011 | 2,093 |
| Prolia® | 1,049 | 586 | 1,635 |
| Sensipar® / Mimpara® | 1,240 | 342 | 1,582 |
| XGEVA® | 1,115 | 414 | 1,529 |
| EPOGEN® | 1,282 | — | 1,282 |
| Other products | 1,913 | 1,245 | 3,158 |
| Total product sales[1] | 17,325 | 4,567 | 21,892 |
| Other revenues | 1,001 | 98 | 1,099 |
| Total revenues[2] | $18,326 | $4,665 | $22,991 |

(1) Hedging gains and losses, which are included in product sales, were not material for the years ended December 31, 2018 and 2017. For the year ended December 31, 2016, hedging gains were $308 million.

(2) Prior-period amounts are not adjusted under the modified-retrospective method of adoption of the new revenue recognition accounting standard.

5. Stock-based compensation

Our Amended and Restated 2009 Equity Incentive Plan (the Amended 2009 Plan) authorizes for issuance to employees of Amgen, employees of Amgen subsidiaries and nonemployee members of our Board of Directors shares of our common stock pursuant to grants of equity-based awards, including RSUs, stock options and performance units. The pool of shares available under the Amended 2009 Plan is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including RSUs and performance units (full-value awards). In general, if any shares subject to an award granted under the Amended 2009 Plan expire or become forfeited, terminated or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, under the Amended 2009 Plan, shares withheld to pay for minimum statutory tax obligations with respect to full-value awards are added back into the authorized pool on the basis of 1.9 shares. As of December 31, 2018, the Amended 2009 Plan provides for future grants and/or issuances of up to 32 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Income (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| RSUs | $165 | $174 | $177 |
| Performance units | 117 | 133 | 123 |
| Stock options | 29 | 22 | 11 |
| Total stock-based compensation expense, pretax | 311 | 329 | 311 |
| Tax benefit from stock-based compensation expense | (67) | (118) | (112) |
| Total stock-based compensation expense, net of tax | $244 | $211 | $199 |

Restricted stock units and stock options

Eligible employees generally receive an annual grant of RSUs and, for certain executive-level employees, stock options, with the size and type of award generally determined by the employee’s salary grade and performance level. In 2016, we reinstated the practice of granting stock options to eligible employees annually, which had been suspended from 2012 through 2015. In addition, certain management and professional-level employees typically receive RSU grants upon commencement of employment. Nonemployee members of our Board of Directors also receive an annual grant of RSUs.

Our RSU and stock option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including upon death, disability, termination in connection with a change in control and the retirement of employees who meet certain service and/or age requirements. RSUs and stock options generally vest in equal amounts on the second, third and fourth anniversaries of the grant date. RSUs accrue dividend equivalents, which are typically payable in shares, only when and to the extent the underlying RSUs vest and are issued to the recipient.

Restricted stock units

The grant date fair value of an RSU equals the closing price of our common stock on the grant date, as RSUs accrue dividend equivalents during their vesting period. The weighted-average grant date fair values of RSUs granted during the years ended December 31, 2018, 2017 and 2016, were $179.18, $163.99 and $156.76, respectively.

The following table summarizes information regarding our RSUs:

| | Year ended December 31, 2018 | |
|---|---|---|
| | Units (in millions) | Weighted-average grant date fair value |
| Balance nonvested at December 31, 2017 | 3.4 | $ 155.11 |
| Granted | 1.2 | $ 179.18 |

| | | |
|---|---|---|
| Vested | (1.2) | $ 142.82 |
| Forfeited | (0.3) | $ 163.36 |
| Balance nonvested at December 31, 2018 | 3.1 | $ 168.11 |

The total grant date fair values of RSUs that vested during the years ended December 31, 2018, 2017 and 2016, were $167 million, $182 million and $193 million, respectively.

As of December 31, 2018, there was $304 million of unrecognized compensation cost related to nonvested restricted stock units and unvested stock options, which is expected to be recognized over a weighted-average period of 1.7 years.

Stock options

The exercise price of stock options is set as the closing price of our common stock on the grant date, and the related number of shares granted is fixed at that point in time. Awards expire 10 years from the date of grant. We use the Black–Scholes option valuation model to estimate the grant date fair value of stock options.

The weighted-average assumptions used in the option valuation model and the resulting weighted-average grant date fair values of stock options granted were as follows:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Closing price of our common stock on grant date | $177.46 | $162.60 | $156.35 |
| Expected volatility (average of implied and historical volatility) | 24.6 % | 22.7 % | 24.3 % |
| Expected life (in years) | 5.8 | 5.8 | 5.8 |
| Risk-free interest rate | 2.8 % | 2.1 % | 1.5 % |
| Expected dividend yield | 2.9 % | 2.8 % | 2.6 % |
| Fair value of stock options granted | $34.60 | $27.54 | $27.55 |

The following table summarizes information regarding our stock options:

| | Year ended December 31, 2018 | | | |
|---|---|---|---|---|
| | Options (in millions) | Weighted-average exercise price | Weighted-average remaining contractual life (in years) | Aggregate intrinsic value (in millions) |
| Balance unexercised at December 31, 2017 | 4.0 | $ 127.08 | | |
| Granted | 1.2 | $ 177.46 | | |
| Exercised | (0.5) | $ 76.68 | | |
| Expired/forfeited | (0.3) | $ 163.79 | | |
| Balance unexercised at December 31, 2018 | 4.4 | $ 143.57 | 7.0 | $ 225 |
| Vested or expected to vest at December 31, 2018 | 4.2 | $ 142.09 | 6.9 | $ 220 |
| Exercisable at December 31, 2018 | 1.2 | $ 84.01 | 3.3 | $ 135 |

The total intrinsic values of options exercised during the years ended December 31, 2018, 2017 and 2016, were $53 million, $60 million and $102 million, respectively. The actual tax benefits realized from tax deductions from option exercises during the years ended December 31, 2018, 2017 and 2016, were $12 million, $21 million and $37 million, respectively.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified preestablished goals over the performance period, which is generally three years. The performance goals for the units granted during the years ended December 31, 2018, 2017 and 2016, which are accounted for as equity awards, are based on (i) Amgen's stockholder return compared with a comparator group of companies, which are considered market conditions and are therefore reflected in the grant date fair values of the units, and (ii) Amgen's stand-alone financial performance measures, which are considered performance conditions. The expense recognized for awards is based on the grant date fair value of a unit multiplied by the number of units expected to be earned with respect to the related performance conditions, net of estimated forfeitures. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, performance unit awards vest at the end of

the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age

requirements. Performance units accrue dividend equivalents that are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market and performance conditions that affect the number of performance units earned.

We use a payout simulation model to estimate the grant date fair value of performance units. The weighted-average assumptions used in this model and the resulting weighted-average grant date fair values of performance units granted were as follows:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Closing price of our common stock on grant date | $177.93 | $162.60 | $156.35 |
| Volatility | 23.8 % | 25.9 % | 25.8 % |
| Risk-free interest rate | 2.6 % | 1.4 % | 0.9 % |
| Fair value of units granted | $189.21 | $178.87 | $170.56 |

The payout simulation model assumes correlations of returns of the stock prices of our common stock and the common stocks of the comparator groups of companies and stock price volatilities of the comparator groups of companies to simulate stockholder returns over the performance periods and their resulting impact on the payout percentages based on the contractual terms of the performance units.

As of December 31, 2018 and 2017, 2.0 million and 2.2 million performance units were outstanding with weighted-average grant date fair values of $180.12 and $177.16 per unit, respectively. During the year ended December 31, 2018, 0.8 million performance units with a weighted-average grant date fair value of $189.21 were granted, and 0.2 million performance units with a weighted-average grant date fair value of $177.95 were forfeited.

The total fair values of performance units that vested during the years ended December 31, 2018, 2017 and 2016 were $133 million, $219 million and $347 million, respectively, based on the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period.

As of December 31, 2018, there was $131 million of unrecognized compensation cost, which is expected to be recognized over a weighted-average period of one year.

6. Defined contribution plan

The Company has defined contribution plans to which employees of the Company and participating subsidiaries may defer compensation for income tax purposes. Participants are eligible to receive matching contributions based on their contributions, in addition to other Company contributions. Defined contribution plan expenses were $173 million, $196 million and $174 million for the years ended December 31, 2018, 2017 and 2016, respectively.

7. Income taxes

On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (2017 Tax Act). The 2017 Tax Act imposes a repatriation tax on accumulated earnings of foreign subsidiaries, imposes a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We have completed our accounting for the tax effects of the 2017 Tax Act, including the repatriation tax, the net deferred tax remeasurement and the impact on our UTBs. None of the adjustments we made to our provisional amounts were material to our consolidated financial statements.

Income before income taxes included the following (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Domestic | $4,856 | $4,436 | $4,478 |
| Foreign | 4,689 | 5,161 | 4,685 |
| Total income before income taxes | $9,545 | $9,597 | $9,163 |

The provision for income taxes included the following (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Current provision: | | | |
| Federal | $1,270 | $8,615 | $984 |
| State | 17 | 5 | 65 |
| Foreign | 227 | 275 | 176 |
| Total current provision | 1,514 | 8,895 | 1,225 |
| Deferred (benefit) provision: | | | |
| Federal | (317) | (1,120) | 372 |
| State | (7) | — | (69) |
| Foreign | (39) | (157) | (87) |
| Total deferred (benefit) provision | (363) | (1,277) | 216 |
| Total provision for income taxes | $1,151 | $7,618 | $1,441 |

Deferred income taxes reflect the tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards and the tax effects of net operating loss (NOL) carryforwards. Significant components of our deferred tax assets and liabilities were as follows (in millions):

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Deferred income tax assets: | | |
| NOL and credit carryforwards | $810 | $812 |
| Accrued expenses | 428 | 362 |
| Expenses capitalized for tax | 185 | 155 |
| Stock-based compensation | 95 | 99 |
| Other | 174 | 154 |
| Total deferred income tax assets | 1,692 | 1,582 |
| Valuation allowance | (509) | (497) |
| Net deferred income tax assets | 1,183 | 1,085 |
| | | |
| Deferred income tax liabilities: | | |
| Acquired intangible assets | (1,509) | (1,748) |
| Debt | (184) | (184) |
| Other | (267) | (240) |
| Total deferred income tax liabilities | (1,960) | (2,172) |
| Total deferred income taxes, net | $(777) | $(1,087) |

Valuation allowances are provided to reduce the amounts of our deferred tax assets to an amount that is more likely than not to be realized based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts.

The valuation allowance increased in 2018 due primarily to the Company’s expectation that some state R&D credits will not be utilized.

As of December 31, 2018, we had $20 million of federal tax credit carryforwards available to reduce future federal income taxes and have provided no valuation allowance for those federal tax credit carryforwards. The federal tax credit carryforwards expire between 2026 and 2035. We had $556 million of state tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $444 million of those state tax credit carryforwards. A portion of the state credits for which no valuation allowance has been provided will expire between 2022 and 2024.

As of December 31, 2018, we had $145 million of federal NOL carryforwards available to reduce future federal income taxes and have provided a valuation allowance for $6 million of those federal NOL carryforwards. The federal NOL carryforwards, for which no valuation allowance has been provided, expire between 2020 and 2035. We had $287 million of state NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for $263 million of those state NOL carryforwards. The state NOLs for which no valuation allowance has been provided expire between 2019 and 2032. We had $1.8 billion of foreign NOL carryforwards available to reduce future foreign income taxes and have provided a valuation allowance for $485 million of those foreign NOL carryforwards. For the foreign NOLs with no valuation allowance provided, $620 million has no expiry; and the remainder will expire between 2019 and 2024.

The reconciliations of the total gross amounts of UTBs (excluding interest, penalties, foreign tax credits and the federal tax benefit of state taxes related to UTBs) were as follows (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Beginning balance | $2,953 | $2,543 | $2,114 |
| Additions based on tax positions related to the current year | 173 | 447 | 425 |
| Additions based on tax positions related to prior years | 13 | 1 | 18 |
| Reductions for tax positions of prior years | (17) | (5) | (7) |
| Reductions for expiration of statute of limitations | — | (5) | — |
| Settlements | (61) | (28) | (7) |
| Ending balance | $3,061 | $2,953 | $2,543 |

Substantially all of the UTBs as of December 31, 2018, if recognized, would affect our effective tax rate. During the year ended December 31, 2018, we effectively settled various examinations with state tax authorities for prior tax years. As a result of these developments, we remeasured our UTBs accordingly.

Interest and penalties related to UTBs are included in our provision for income taxes. During the years ended December 31, 2018, 2017 and 2016, we recognized $137 million, $56 million and $125 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. As of December 31, 2018 and 2017, accrued interest and penalties associated with UTBs were $469 million and $332 million, respectively.

The reconciliations between the federal statutory tax rate applied to income before income taxes and our effective tax rate were as follows:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Federal statutory tax rate | 21.0 % | 35.0 % | 35.0 % |
| 2017 Tax Act, net repatriation tax | — % | 70.7 % | — % |
| Foreign earnings | (4.3)% | (15.8)% | (15.5)% |
| 2017 Tax Act, net deferred tax remeasurement | — % | (6.9)% | — % |
| Credits, Puerto Rico Excise Tax | (2.5)% | (2.2)% | (2.3)% |
| 2017 Tax Act, net impact on intercompany sales | (1.8)% | — % | — % |
| Interest on uncertain tax positions | 1.2 % | 0.6 % | 0.5 % |
| Credits, primarily federal R&D | (0.8)% | (0.6)% | (0.7)% |
| Share-based payments | (0.2)% | (0.7)% | (1.3)% |
| Other, net | (0.5)% | (0.7)% | — % |
| Effective tax rate | 12.1 % | 79.4 % | 15.7 % |

The effective tax rate for the year ended December 31, 2018 differs from the federal statutory rate due primarily to impacts of the jurisdictional mix of income and expenses. The effective tax rate for 2017 differs from the federal statutory rate primarily as a result of the 2017 Tax Act. The effective tax rate for 2016 differs from the federal statutory rate primarily as a result of indefinitely invested earnings of our foreign operations. Substantially all of the benefit to our effective tax rate from foreign earnings results from the Company’s operations conducted in Puerto Rico,

a territory of the United States that is treated as a foreign

jurisdiction for U.S. tax purposes and is subject to tax incentive grants through 2035; these earnings are also subject to U.S. tax at a reduced 10.5% rate.

The U.S. territory of Puerto Rico imposes an excise tax on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico. The rate of 4% is effective through December 31, 2027. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

Income taxes paid during the years ended December 31, 2018, 2017 and 2016, were $1.9 billion, $1.5 billion and $1.1 billion, respectively.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by the tax authorities in those jurisdictions. Significant disputes may arise with authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and the interpretation of the relevant facts. As previously disclosed, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. In November 2017, we received a modified RAR that revised the IRS's calculation but continued to propose substantial adjustments. We disagree with the proposed adjustments and are pursuing resolution with the IRS administrative appeals office, which currently has jurisdiction over the matter. If we deem necessary, we will vigorously contest the proposed adjustments through the judicial process. Final resolution of this complex matter is not likely within the next 12 months and could have a material impact on our consolidated financial statements. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009. In addition, we are currently under examination by a number of other state and foreign tax jurisdictions.

8. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which include primarily shares that may be issued under our stock option, restricted stock and performance unit award programs, as determined by using the treasury stock method (collectively, dilutive securities).

The computations for basic and diluted EPS were as follows (in millions, except per-share data):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Income (Numerator): | | | |
| Net income for basic and diluted EPS | $8,394 | $1,979 | $7,722 |
| | | | |
| Shares (Denominator): | | | |
| Weighted-average shares for basic EPS | 661 | 731 | 748 |
| Effect of dilutive securities | 4 | 4 | 6 |
| Weighted-average shares for diluted EPS | 665 | 735 | 754 |
| | | | |
| Basic EPS | $12.70 | $2.71 | $10.32 |
| Diluted EPS | $12.62 | $2.69 | $10.24 |

For each of the three years ended December 31, 2018, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

9. Collaborations

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. Such arrangements involve two or more parties that are both (i) active participants in the activity and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for nonrefundable upfront license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration arrangements are performed with no guarantee of either technological or commercial success, and each is unique in nature. See Note 1, Summary of significant accounting policies, for additional discussion of revenues recognized for these types of arrangements. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line items in the consolidated statements of income, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. Our significant arrangements are discussed below.

Novartis AG

In April 2017, we expanded our existing migraine collaboration with Novartis AG (Novartis). In the United States, Amgen and Novartis jointly develop and collaborate on the commercialization of Aimovig® (erenumab-aooe). Amgen, as the principal, recognizes product sales of Aimovig® in the United States, shares U.S. commercialization costs with Novartis and pays Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan for Aimovig® and other specified migraine programs. Novartis pays Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories and funds a portion of global R&D expenses. In addition, Novartis will make a payment to Amgen of up to $100 million if certain commercial and expenditure thresholds are achieved with respect to Aimovig® in the United States. Amgen manufactures and supplies Aimovig® worldwide.

The migraine collaboration will continue for the commercial lives of the products unless terminated in accordance with its terms.

During the year ended December 31, 2018, net costs paid to Novartis for migraine products were $44 million and were recorded primarily in Selling, general and administrative expense in the Consolidated Statements of Income. During the years ended December 31, 2017 and 2016, net costs recovered from Novartis for the migraine products were $124 million and $33 million, respectively, and were recorded primarily in Research and development expense in the Consolidated Statements of Income. During the year ended December 31, 2018, royalties due to Novartis for the migraine products were $43 million and were recorded in Cost of sales in the Consolidated Statements of Income. As a result of certain regulatory and commercial events, we received milestone payments from Novartis of $295 million and $60 million during the years ended December 31, 2018 and 2017, respectively, which were recorded in Other revenues in the Consolidated Statements of Income.

UCB

We are in a collaboration with UCB for the development and commercialization of EVENITY™ (romosozumab). Under our collaboration, UCB has the rights to lead commercialization for EVENITY™ for all indications in Europe, China (excluding Hong Kong) and Brazil. All other territories have been allocated to Amgen. Generally, development costs and future worldwide commercialization profits and losses related to the collaboration after accounting for expenses are shared equally. The collaboration agreement will continue in effect unless terminated earlier in accordance with its terms. During the years ended December 31, 2018, 2017 and 2016, net costs recovered from UCB were not material and were recorded primarily in Research and development expense in the Consolidated Statements of Income.

Bayer HealthCare Pharmaceuticals Inc.

We are in a collaboration with Bayer HealthCare Pharmaceuticals Inc. (Bayer) to jointly develop and commercialize Nexavar® (sorafenib) worldwide, except in Japan. The rights to develop and market Nexavar® in Japan are reserved to Bayer. Nexavar® is currently marketed and sold in more than 100 countries around the world for the treatment of unresectable liver cancer and advanced kidney cancer. In the United States, Nexavar® is also approved for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to

radioactive iodine treatment.

In 2015, we amended the terms of our collaboration agreement with Bayer, which terminated the co-promotion agreement in the United States and transferred all U.S. operational responsibilities to Bayer, including commercial and medical affairs activities. Prior to the termination of the co-promotion agreement, we co-promoted Nexavar® with Bayer and shared equally in the profits or losses in the United States. In lieu of this profit share, Bayer now pays Amgen a royalty on U.S. sales of Nexavar® at a percentage rate in the high 30s. Amgen no longer contributes sales force personnel or medical liaisons to support Nexavar®

in the United States. There are no changes to the global R&D or non-U.S. profit share arrangements in the original agreement, as discussed below.

In all countries outside the United States, excluding Japan, Bayer manages all commercialization activities and incurs all of the sales and marketing expenditures and mutually agreed R&D expenses, for which we continue to reimburse Bayer for half. In these countries, we continue to receive 50% of net profits on sales of Nexavar® after deducting certain Bayer-related costs.

The agreement with Bayer will terminate at the later of the date when patents expire that were issued in connection with product candidates discovered under the agreement or on the last day that we or Bayer market or sell products commercialized under the agreement anywhere in the world. Patents related to Nexavar® begin to expire in 2020.

During the years ended December 31, 2018, 2017 and 2016, Amgen recorded Nexavar® net profits of $164 million, $161 million and $167 million, respectively, which were recognized as Other revenues in the Consolidated Statements of Income. During the years ended December 31, 2018, 2017 and 2016, Amgen recorded royalty income of $91 million, $133 million and $137 million, respectively, in Other revenues in the Consolidated Statements of Income, pursuant to the 2015 amendment to the collaboration agreement. Net R&D expenses related to the agreement were not material for the years ended December 31, 2018, 2017 and 2016.

Other

In addition to the collaborations discussed above, we have various others that are not individually significant to our business at this time. Pursuant to the terms of those agreements, we may be required to pay or we may receive additional amounts upon the achievement of various development and commercial milestones, which in the aggregate could be significant. We may also incur or have reimbursed to us significant R&D costs if the related product candidate were to advance to late-stage clinical trials. In addition, if any products related to these collaborations are approved for sale, we may be required to pay or we may receive significant royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurrence.

10. Related party transactions

As of December 31, 2017, we owned a 50% interest in K-A, a corporation formed in 1984 with Kirin for the development and commercialization of certain products based on advanced biotechnology. All of our rights to manufacture and market certain products including pegfilgrastim, filgrastim, darbepoetin alfa, recombinant human erythropoietin and romiplostim are pursuant to exclusive licenses from K-A, which we currently market under the brand names Neulasta®, NEUPOGEN® (filgrastim)/GRANULOKINE®, Aranesp®, EPOGEN® and Nplate® (romiplostim), respectively. During the first quarter of 2018, we acquired the remaining 50% ownership of K-A from Kirin, making K-A a wholly owned subsidiary of Amgen. The transaction was accounted for as a business combination. K-A's results of operations are now included in our consolidated financial statements, and as a result, transactions between us and K-A are eliminated in consolidation. See Note 3, Business combinations. License agreements with Kirin and Johnson & Johnson (J&J) remain in place.

Prior to the share acquisition, we accounted for our interest in K-A using the equity method and included our share of K-A's profits or losses in Selling, general and administrative expense in the Consolidated Statements of Income. Our share of K-A's profits was insignificant for the period January 1, 2018 through the 2018 share acquisition date. For the years ended December 31, 2017 and 2016, our share of K-A's profits was $68 million and $58 million, respectively. The carrying value of our equity method investment in K-A was $570 million as of December 31, 2017, and is included in Other assets in the Consolidated Balance Sheets.

K-A's revenues consist of royalty income related to its licensed technology rights. Prior to the share acquisition, K-A received royalty income from us. K-A also received and continues to receive royalty income from Kirin and J&J under separate product license contracts for certain geographic areas outside the United States. Royalties earned by K-A from us were insignificant for the period January 1, 2018 through the 2018 share acquisition date. During the years ended December 31, 2017 and 2016, K-A earned royalties from us of $221 million and $239 million, respectively. These amounts are included in Cost of sales in the Consolidated Statements of Income.

K-A's expenses consist primarily of costs related to R&D activities conducted on its behalf by us through the 2018 share acquisition and by Kirin. Payment for these services is based on negotiated rates. Revenues from K-A for certain

R&D activities performed on K-A's behalf were insignificant for the period January 1, 2018 through the 2018 share acquisition date. During the years ended December 31, 2017 and 2016, we earned revenues from K-A of $28 million and $31 million, respectively, for certain R&D activities performed on K-A's behalf. These amounts were recognized as Other revenues in the Consolidated Statements of

Income. Cost recoveries from K-A recorded during the period January 1, 2018 through the 2018 share acquisition date and the years ended December 31, 2017 and 2016, were insignificant. These amounts are included in Research and development expense in the Consolidated Statements of Income.

As of December 31, 2017, we owed K-A $80 million, which is included in Accrued liabilities in the Consolidated Balance Sheets.

11. Investments

Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and fair values of available-for-sale investments by type of security were as follows (in millions):

| Types of securities as of December 31, 2018 | Amortized cost | Gross unrealized gains | Gross unrealized losses | Fair values |
|---|---|---|---|---|
| U.S. Treasury notes | $ 2,710 | $ — | $ (47) | $2,663 |
| U.S. Treasury bills | 8,191 | — | — | 8,191 |
| Other government-related debt securities: | | | | |
| U.S. | 112 | — | (2) | 110 |
| Foreign and other | 972 | 1 | (41) | 932 |
| Corporate debt securities: | | | | |
| Financial | 2,778 | — | (81) | 2,697 |
| Industrial | 2,603 | — | (99) | 2,504 |
| Other | 583 | — | (21) | 562 |
| Residential-mortgage-backed securities | 1,458 | — | (36) | 1,422 |
| Other mortgage- and asset-backed securities | 483 | — | (14) | 469 |
| Money market mutual funds | 5,659 | — | — | 5,659 |
| Other short-term interest-bearing securities | 3,515 | — | — | 3,515 |
| Total available-for-sale investments | $ 29,064 | $ 1 | $ (341) | $28,724 |

| Types of securities as of December 31, 2017 | Amortized cost | Gross unrealized gains | Gross unrealized losses | Fair values |
|---|---|---|---|---|
| U.S. Treasury notes | $ 8,313 | $ 1 | $ (72) | $8,242 |
| Other government-related debt securities: | | | | |
| U.S. | 225 | — | (2) | 223 |
| Foreign and other | 2,415 | 18 | (11) | 2,422 |
| Corporate debt securities: | | | | |
| Financial | 10,089 | 17 | (34) | 10,072 |
| Industrial | 9,688 | 34 | (52) | 9,670 |
| Other | 1,393 | 3 | (6) | 1,390 |
| Residential-mortgage-backed securities | 2,198 | — | (30) | 2,168 |
| Other mortgage- and asset-backed securities | 2,312 | — | (15) | 2,297 |
| Money market mutual funds | 3,245 | — | — | 3,245 |
| Other short-term interest-bearing securities | 1,440 | — | — | 1,440 |
| Total interest-bearing securities | 41,318 | 73 | (222) | 41,169 |
| Equity securities | 135 | 14 | — | 149 |
| Total available-for-sale investments | $ 41,453 | $ 87 | $ (222) | $41,318 |

The fair values of available-for-sale investments by location in the Consolidated Balance Sheets were as follows (in millions):

| | December 31, | |
|---|---|---|
| Consolidated Balance Sheets locations | 2018 | 2017 |
| Cash and cash equivalents | $6,365 | $3,291 |
| Marketable securities | 22,359 | 37,878 |
| Other assets | — | 149 |
| Total available-for-sale investments | $28,724 | $41,318 |

Cash and cash equivalents in the above table excludes bank account cash of $580 million and $509 million as of December 31, 2018 and 2017, respectively. Other assets as of December 31, 2017, consisted of equity securities, which are no longer classified as available-for-sale.

As a result of the adoption of the new accounting standard related to the classification and measurement of financial instruments on January 1, 2018, equity investments (except for investments accounted for under the equity method of accounting) are now measured at fair value, with changes in fair value recognized in earnings. These investments were previously measured at fair value, with changes in fair value recognized in AOCI. Accordingly, these securities are no longer classified as available-for-sale and their presentation is not comparable to the presentation as of December 31, 2017. See Equity securities, discussed below, and Note 1, Summary of significant accounting policies.

The fair values of available-for-sale interest-bearing security investments by contractual maturity, except for mortgage- and asset-backed securities that do not have a single maturity date, were as follows (in millions):

| | December 31, | |
|---|---|---|
| Contractual maturities | 2018 | 2017 |
| Maturing in one year or less | $17,424 | $6,733 |
| Maturing after one year through three years | 3,356 | 12,820 |
| Maturing after three years through five years | 5,168 | 13,836 |
| Maturing after five years through ten years | 885 | 3,263 |
| Maturing after ten years | — | 52 |
| Mortgage- and asset-backed securities | 1,891 | 4,465 |
| Total interest-bearing securities | $28,724 | $41,169 |

For the years ended December 31, 2018, 2017 and 2016, realized gains on interest-bearing securities were $29 million, $147 million and $304 million, respectively, and realized losses on interest-bearing securities were $394 million, $213 million and $367 million, respectively. Realized gains and losses on interest-bearing securities are recorded in Interest and other income, net, in the Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

The fair values and gross unrealized losses of available-for-sale investments in an unrealized loss position aggregated by type and length of time that the securities have been in a continuous loss position were as follows (in millions):

| | Less than 12 months | | 12 months or more | |
|---|---|---|---|---|
| Types of securities as of December 31, 2018 | Fair values | Unrealized losses | Fair values | Unrealized losses |
| U.S. Treasury notes | $1,219 | $ (21) | $1,444 | $ (26) |
| Other government-related debt securities: | | | | |
| U.S. | — | — | 110 | (2) |
| Foreign and other | 631 | (31) | 240 | (10) |
| Corporate debt securities: | | | | |
| Financial | 1,968 | (59) | 718 | (22) |
| Industrial | 1,898 | (81) | 529 | (18) |
| Other | 529 | (20) | 28 | (1) |
| Residential-mortgage-backed securities | 576 | (14) | 840 | (22) |
| Other mortgage- and asset-backed securities | 17 | — | 451 | (14) |
| Total | $6,838 | $ (226) | $4,360 | $ (115) |

| | Less than 12 months | | 12 months or more | |
|---|---|---|---|---|
| Types of securities as of December 31, 2017 | Fair values | Unrealized losses | Fair values | Unrealized losses |
| U.S. Treasury notes | $7,728 | $ (70) | $195 | $ (2) |
| Other government-related debt securities: | | | | |
| U.S. | 188 | (1) | 34 | (1) |
| Foreign and other | 1,163 | (9) | 115 | (2) |
| Corporate debt securities: | | | | |
| Financial | 5,928 | (28) | 462 | (6) |
| Industrial | 5,760 | (43) | 612 | (9) |
| Other | 868 | (4) | 117 | (2) |
| Residential-mortgage-backed securities | 1,838 | (24) | 276 | (6) |
| Other mortgage- and asset-backed securities | 1,777 | (12) | 250 | (3) |
| Total | $25,250 | $ (191) | $2,061 | $ (31) |

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. The evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below our cost basis, as well as adverse conditions related specifically to the security such as any changes to the credit rating of the security and the intent to sell or whether we will more likely than not be required to sell the security before recovery of its amortized cost basis. Our assessment of whether a security is other-than-temporarily impaired could change in the future based on new developments or changes in assumptions related to that particular security. As of December 31, 2018, unrealized losses on available-for-sale investments were due primarily to higher interest rates on that date than at the time the securities were purchased. As of December 31, 2018 and 2017, we believe the cost bases for our available-for-sale investments were recoverable in all material respects.

Equity securities

We held investments in equity securities with readily determinable fair values of $176 million and $149 million as of December 31, 2018 and 2017, respectively, which are included in Other assets in the Consolidated Balance Sheets. As a result of the adoption of the new accounting standard related to the classification and measurement of financial instruments on January 1, 2018, equity investments (except for investments accounted for under the equity method of accounting) are now measured at fair value, with changes in fair value recognized in earnings. These investments were previously measured at fair value, with changes in fair value recognized in AOCI. Accordingly, these securities are no longer classified as available-for-sale and their presentation is not comparable to the presentation as of December 31, 2017. See Available-for-sale investments, discussed above, and Note 1, Summary of significant accounting policies. Gains and losses recognized on equity securities with readily determinable fair values, including gains and losses recognized on sales, were not material for the years ended December 31, 2018, 2017 and 2016.

We held investments in equity securities without readily determinable fair values of $222 million and $95 million as of December 31, 2018 and 2017, respectively, which are included in Other assets in the Consolidated Balance Sheets. Adjustments to the carrying values of these securities were not material for the years ended December 31, 2018, 2017 and 2016.

Limited partnership investments

We held limited partnership investments of $285 million and $213 million as of December 31, 2018 and 2017, respectively, which are included in Other assets in the Consolidated Balance Sheets. These investments are measured by using the net asset values of the underlying investments as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of December 31, 2018, unfunded additional commitments to be made during the next several years for these investments were not material. Gains and losses recognized on our limited partnership investments were not material for the years ended December 31, 2018, 2017 and 2016.

12. Inventories

Inventories consisted of the following (in millions):

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Raw materials | $257 | $232 |
| Work in process | 1,660 | 1,668 |
| Finished goods | 1,023 | 934 |
| Total inventories | $2,940 | $2,834 |

13. Property, plant and equipment

Property, plant and equipment consisted of the following (dollar amounts in millions):

| | | December 31, | |
|---|---|---|---|
| | Useful life (in years) | 2018 | 2017 |
| Land | — | $265 | $283 |
| Buildings and improvements | 10-40 | 3,616 | 3,507 |
| Manufacturing equipment | 8-12 | 2,418 | 2,372 |
| Laboratory equipment | 8-12 | 1,174 | 1,179 |
| Capitalized software | 3-5 | 1,124 | 1,150 |
| Other | 3-15 | 3,204 | 3,254 |
| Construction in progress | — | 953 | 834 |
| Property, plant and equipment, gross | | 12,754 | 12,579 |
| Less accumulated depreciation and amortization | | (7,796 ) | (7,590 ) |
| Property, plant and equipment, net | | $4,958 | $4,989 |

During the years ended December 31, 2018, 2017 and 2016, we recognized depreciation and amortization expense associated with our property, plant and equipment of $630 million, $604 million and $619 million, respectively.

Geographic information

Certain geographic information with respect to property, plant and equipment, net (long-lived assets), was as follows (in millions):

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| United States | $2,373 | $2,349 |
| Puerto Rico | 1,476 | 1,527 |
| ROW | 1,109 | 1,113 |
| Total property, plant and equipment, net | $4,958 | $4,989 |

14. Goodwill and other intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in millions):

| | Years ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Beginning balance | $14,761 | $14,751 |
| Addition from K-A acquisition | 6 | — |
| Currency translation adjustments | (68) | 10 |
| Ending balance | $14,699 | $14,761 |

Other intangible assets

Other intangible assets consisted of the following (in millions):

| | December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2018 | | | 2017 | | |
| | Gross carrying amounts | Accumulated amortization | Other intangible assets, net | Gross carrying amounts | Accumulated amortization | Other intangible assets, net |
| Finite-lived intangible assets: | | | | | | |
| Developed-product-technology rights | $12,573 | $ (7,479) | $ 5,094 | $12,589 | $ (6,796) | $ 5,793 |
| Licensing rights | 3,772 | (2,032) | 1,740 | 3,275 | (1,601) | 1,674 |
| Marketing-related rights | 1,297 | (1,019) | 278 | 1,319 | (920) | 399 |
| R&D technology rights | 1,148 | (872) | 276 | 1,161 | (804) | 357 |
| Total finite-lived intangible assets | 18,790 | (11,402) | 7,388 | 18,344 | (10,121) | 8,223 |
| Indefinite-lived intangible assets: | | | | | | |
| IPR&D | 55 | — | 55 | 386 | — | 386 |
| Total other intangible assets | $18,845 | $ (11,402) | $ 7,443 | $18,730 | $ (10,121) | $ 8,609 |

Developed-product-technology rights consist of rights related to marketed products acquired in business combinations. Licensing rights consist primarily of contractual rights acquired in business combinations to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and upfront payments associated with royalty obligations for marketed products. Licensing rights increased in 2018 due to the K-A share acquisition. See Note 3, Business combinations. Marketing-related rights assets consist primarily of rights related to the sale and distribution of marketed products. R&D technology rights consist of technology used in R&D with alternative future uses.

IPR&D consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. During 2018, we discontinued the internal development of a non-key program, resulting in an impairment charge of $330 million, which was recognized in Other operating expenses in the Consolidated Statements of Income and included in Other items, net, in the Consolidated Statements of Cash Flows.

All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of the development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require the completion of clinical trials that demonstrate that a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans as well as competitive product launches, affect the revenues a product can generate. Consequently, the eventual realized value, if any, of acquired IPR&D projects may vary from their estimated fair values. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During the years ended December 31, 2018, 2017 and 2016, we recognized amortization expenses associated with our finite-lived intangible assets of $1.3 billion, $1.3 billion and $1.5 billion, respectively. Amortization of intangible assets is included primarily in Cost of sales in the Consolidated Statements of Income. The total estimated amortization expenses for our finite-lived intangible assets for each of the next five years are $1.3 billion, $1.2 billion, $1.0 billion, $0.9 billion and $0.9 billion in 2019, 2020, 2021, 2022 and 2023, respectively.

15. Accrued liabilities

Accrued liabilities consisted of the following (in millions):

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Sales deductions | $3,170 | $2,247 |
| Employee compensation and benefits | 1,001 | 816 |
| Dividends payable | 914 | 953 |
| Sales returns reserve | 535 | 455 |
| Other | 2,242 | 2,045 |
| Total accrued liabilities | $7,862 | $6,516 |

16. Financing arrangements

Our borrowings consisted of the following (in millions):

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| 6.15% notes due 2018 (6.15% 2018 Notes) | $— | $500 |
| 4.375% €550 million notes due 2018 (4.375% 2018 euro Notes) | — | 653 |
| 5.70% notes due 2019 (5.70% 2019 Notes) | 1,000 | 1,000 |
| 1.90% notes due 2019 (1.90% 2019 Notes) | 700 | 700 |
| Floating Rate Notes due 2019 | 550 | 550 |
| 2.20% notes due 2019 (2.20% 2019 Notes) | 1,400 | 1,400 |
| 2.125% €675 million notes due 2019 (2.125% 2019 euro Notes) | 774 | 810 |
| 4.50% notes due 2020 (4.50% 2020 Notes) | 300 | 300 |
| 2.125% notes due 2020 (2.125% 2020 Notes) | 750 | 750 |
| Floating Rate Notes due 2020 | 300 | 300 |
| 2.20% notes due 2020 (2.20% 2020 Notes) | 700 | 700 |
| 3.45% notes due 2020 (3.45% 2020 Notes) | 900 | 900 |
| 4.10% notes due 2021 (4.10% 2021 Notes) | 1,000 | 1,000 |
| 1.85% notes due 2021 (1.85% 2021 Notes) | 750 | 750 |
| 3.875% notes due 2021 (3.875% 2021 Notes) | 1,750 | 1,750 |
| 1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes) | 1,433 | 1,501 |
| 2.70% notes due 2022 (2.70% 2022 Notes) | 500 | 500 |
| 2.65% notes due 2022 (2.65% 2022 Notes) | 1,500 | 1,500 |
| 3.625% notes due 2022 (3.625% 2022 Notes) | 750 | 750 |
| 0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds) | 713 | 719 |
| 2.25% notes due 2023 (2.25% 2023 Notes) | 750 | 750 |
| 3.625% notes due 2024 (3.625% 2024 Notes) | 1,400 | 1,400 |
| 3.125% notes due 2025 (3.125% 2025 Notes) | 1,000 | 1,000 |
| 2.00% €750 million notes due 2026 (2.00% 2026 euro Notes) | 860 | 901 |
| 2.60% notes due 2026 (2.60% 2026 Notes) | 1,250 | 1,250 |
| 5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes) | 606 | 642 |
| 3.20% notes due 2027 (3.20% 2027 Notes) | 1,000 | 1,000 |
| 4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes) | 893 | 946 |
| 6.375% notes due 2037 (6.375% 2037 Notes) | 552 | 552 |
| 6.90% notes due 2038 (6.90% 2038 Notes) | 291 | 291 |
| 6.40% notes due 2039 (6.40% 2039 Notes) | 466 | 466 |
| 5.75% notes due 2040 (5.75% 2040 Notes) | 412 | 412 |
| 4.95% notes due 2041 (4.95% 2041 Notes) | 600 | 600 |
| 5.15% notes due 2041 (5.15% 2041 Notes) | 974 | 974 |
| 5.65% notes due 2042 (5.65% 2042 Notes) | 487 | 487 |
| 5.375% notes due 2043 (5.375% 2043 Notes) | 261 | 261 |
| 4.40% notes due 2045 (4.40% 2045 Notes) | 2,250 | 2,250 |
| 4.563% notes due 2048 (4.563% 2048 Notes) | 1,415 | 1,415 |
| 4.663% notes due 2051 (4.663% 2051 Notes) | 3,541 | 3,541 |
| Other notes due 2097 | 100 | 100 |
| Unamortized discounts, premiums, issuance costs and fair value adjustments, net | (949) | (929) |
| Total carrying value of debt | 33,929 | 35,342 |
| Less current portion | (4,419) | (1,152) |
| Total long-term debt | $29,510 | $34,190 |

There are no material differences between the effective interest rates and coupon rates of any of our borrowings, except for the 4.563% 2048 Notes and the 4.663% 2051 Notes, which have effective interest rates of 6.3% and 5.6%, respectively.

Under the terms of all of our outstanding notes—including debt exchange issuances, discussed below, and except our Other notes due 2097—in the event of a change-in-control triggering event we may be required to purchase all or a portion of these debt securities at prices equal to 101% of the principal amounts of the notes plus accrued and unpaid interest. In addition, all of our outstanding notes—except our floating-rate notes, 0.41% 2023 Swiss franc Bonds and Other notes due 2097—may be redeemed at any time at our option—in whole or in part—at the principal amounts of the notes being redeemed plus accrued and unpaid

interest and make-whole amounts, which are defined by the terms of the notes. Certain of the redeemable notes do not require the payment of make-whole amounts if redeemed during a specified period of time immediately prior to the maturity of the notes. Such time periods range from one to six months prior to maturity.

Debt issuances

We did not issue any debt or debt securities during the year ended December 31, 2018. We issued debt and debt securities in various offerings during the years ended December 31, 2017 and 2016 as follows:

- In 2017, we issued $4.5 billion principal amount of notes, consisting of the Floating Rate Notes due 2019, the 1.90% 2019 Notes, the Floating Rate Notes due 2020, the 2.20% 2020 Notes, the 2.65% 2022 Notes and the 3.20% 2027 Notes.
- In 2016, we issued $6.7 billion principal amount of notes, consisting of the 1.85% 2021 Notes, the 1.25% 2022 euro Notes, the 0.41% 2023 Swiss franc Bonds, the 2.25% 2023 Notes, the 2.00% 2026 euro Notes and the 2.60% 2026 Notes and $1.0 billion of the 4.40% 2045 Notes. We received a $79 million premium on the 4.40% 2045 Notes. In addition, we borrowed $605 million under a short-term floating-rate loan.

As of December 31, 2018, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working-capital needs. During the year ended December 31, 2017, we issued and repaid an aggregate of $12.3 billion of commercial paper and had a maximum outstanding balance of $1.5 billion under our commercial paper program. During the years ended December 31, 2018 and 2016, we did not issue any commercial paper. No commercial paper was outstanding as of December 31, 2018 or 2017.

Debt repayments

In 2018, we repaid $1.1 billion of debt, including the $500 million aggregate principal amount of the 6.15% 2018 Notes and the €550 million aggregate principal amount of the 4.375% 2018 Notes revalued at $621 million upon maturity. In 2017, we repaid $4.4 billion of debt, including the $605 million short-term floating-rate loan, the $1.25 billion aggregate principal amount of the 2.125% 2017 Notes, the $600 million aggregate principal amount of the Floating Rate Notes due 2017, the $850 million aggregate principal amount of the 1.25% 2017 Notes and the $1.1 billion aggregate principal amount of the 5.85% 2017 Notes. In 2016, we repaid $3.7 billion of debt, including the remaining $1.975 billion of principal on a term loan credit facility, the $750 million aggregate principal amount of the 2.30% 2016 Notes and the $1.0 billion aggregate principal amount of the 2.50% 2016 Notes.

Debt exchange

During 2016, we completed a private offering to exchange portions of certain outstanding senior notes due 2037 through 2043 (collectively, the Old Notes), for new senior notes, consisting of principal amounts of $1.4 billion of 4.563% 2048 Notes and $3.5 billion of 4.663% 2051 Notes (collectively, the New Notes).

The New Notes bear lower fixed-coupon rates while requiring higher principal repayments on extended maturity dates compared with the Old Notes that were exchanged. There were no other significant changes to the terms between the Old Notes and the New Notes. The exchange was accounted for as a debt modification, and there were no cash payments to or cash receipts from the noteholders as a result of the exchange. Existing deferred financing costs associated with the Old Notes as well as discounts associated with the New Notes aggregating $801 million are being accreted over the term of the New Notes and recorded as Interest expense, net, in the Consolidated Statements of Income. Transaction costs of $24 million incurred for the exchange were expensed immediately in Interest and other income, net, in the Consolidated Statements of Income.

Interest rate swaps

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted fixed-rate interest coupons for certain of our debt issuances to floating London Interbank Offered Rate (LIBOR)-based coupons over the lives of the respective notes. These interest rate swap contracts qualified and are designated as fair value hedges.

The effective interest rates on notes for which we have entered into interest rate swap contracts and the related notional amounts of these contracts were as follows (dollar amounts in millions):

| | | December 31, | |
|---|---|---|---|
| | | 2018 | 2017 |
| Notes | Effective interest rates | Notional amounts | |
| 2.20% 2019 Notes | LIBOR + 0.6% | $1,400 | $1,400 |
| 3.45% 2020 Notes | LIBOR + 1.1% | 900 | 900 |
| 4.10% 2021 Notes | LIBOR + 1.7% | 1,000 | 1,000 |
| 3.875% 2021 Notes | LIBOR + 2.0% | 1,750 | 1,750 |
| 3.625% 2022 Notes | LIBOR + 1.6% | 750 | 750 |
| 3.625% 2024 Notes | LIBOR + 1.4% | 1,400 | 1,400 |
| 3.125% 2025 Notes | LIBOR + 0.9% | 1,000 | 1,000 |
| 2.600% 2026 Notes | LIBOR + 0.3% | 1,250 | 1,250 |
| 4.663% 2051 Notes | LIBOR + 0.0% | 1,500 | — |
| Total notional amounts | | $10,950 | $9,450 |

Cross-currency swaps

In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts effectively convert the interest payments and principal repayment on our 2.125% 2019 euro Notes, 1.25% 2022 euro Notes, 0.41% 2023 Swiss franc Bonds, 2.00% 2026 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros, pounds sterling and Swiss francs to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 19, Derivative instruments.

Shelf registration statements and other facilities

In 2014, we entered into a $2.5 billion syndicated, unsecured, revolving credit agreement, which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $500 million with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. We extended this term by one year during 2016 and may extend the term for an additional year with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest at LIBOR plus 1% for any amounts borrowed under this facility. As of December 31, 2018 and 2017, no amounts were outstanding under this facility.

In 2017, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in February 2020.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant, which was modified during 2018. The modified covenant requires that we maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest expense, each as defined and described in the amended credit agreement. We were in compliance with all applicable covenants under these arrangements as of December 31, 2018.

Contractual maturities of debt obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2018, are as follows (in millions):

| Maturity dates | Amounts |
|---|---|
| 2019 | $4,424 |
| 2020 | 2,950 |
| 2021 | 3,500 |
| 2022 | 4,183 |
| 2023 | 1,463 |
| Thereafter | 18,358 |
| Total | $34,878 |

Interest costs

Interest costs are expensed as incurred except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest costs capitalized for the years ended December 31, 2018, 2017 and 2016, were not material. Interest paid, including the ongoing impact of interest rate and cross-currency swap contracts, during the years ended December 31, 2018, 2017 and 2016, was $1.5 billion, $1.3 billion and $1.2 billion, respectively.

17. Stockholders' equity

Stock repurchase program

Activity under our stock repurchase program, on a trade date basis, was as follows (in millions):

| | Years ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2018 | | 2017 | | 2016 | |
| | Shares* | Dollars | Shares | Dollars | Shares | Dollars |
| First quarter | 56.4 | $10,787 | 3.4 | $555 | 4.7 | $690 |
| Second quarter | 18.2 | 3,190 | 6.2 | 1,006 | 3.9 | 591 |
| Third quarter | 8.7 | 1,713 | 4.4 | 769 | 4.4 | 747 |
| Fourth quarter | 11.1 | 2,165 | 4.5 | 796 | 6.7 | 999 |
| Total stock repurchases | 94.5 | $17,855 | 18.5 | $3,126 | 19.7 | $3,027 |

* Total shares do not add due to rounding.

In January, April and December 2018, our Board of Directors increased the amount authorized under our stock repurchase program by $10.0 billion, $5.0 billion and $3.6 billion, respectively. Repurchase activity for the year ended December 31, 2018, included 52.1 million shares of our common stock acquired under a tender offer at an aggregate cost of $10.0 billion. As of December 31, 2018, $5.1 billion remained available under our stock repurchase program.

Dividends

Our Board of Directors declared quarterly dividends per share of $1.32, $1.15 and $1.00, which were paid in each of the four quarters of 2018, 2017, and 2016, respectively.

Historically, we have declared dividends in December of each year, which were paid in the first quarter of the following fiscal year, and in March, July and October, which were paid in the second, third and fourth quarters, respectively, of the same fiscal year. Additionally, on December 7, 2018, the Board of Directors declared a quarterly cash dividend of $1.45 per share of common stock, which will be paid on March 8, 2019, to all stockholders of record as of the close of business on February 15, 2019.

Accumulated other comprehensive income (loss)
The components of AOCI were as follows (in millions):

| | Foreign currency translation | Cash flow hedges | Available-for-sale securities | Other | AOCI |
|---|---|---|---|---|---|
| Balance as of December 31, 2015 | $ (511) | $ 297 | $ (260) | $ (6) | $ (480) |
| Foreign currency translation adjustments | (93) | — | — | — | (93) |
| Unrealized (losses) gains | — | (176) | 63 | — | (113) |
| Reclassification adjustments to income | — | 139 | 61 | — | 200 |
| Other | — | — | — | 1 | 1 |
| Income taxes | (6) | 22 | (2) | — | 14 |
| Balance as of December 31, 2016 | (610) | 282 | (138) | (5) | (471) |
| Foreign currency translation adjustments | 77 | — | — | — | 77 |
| Unrealized gains (losses) | — | 192 | (46) | — | 146 |
| Reclassification adjustments to income | — | (638) | 41 | — | (597) |
| Other | — | — | — | 5 | 5 |
| Income taxes | 4 | 158 | (1) | — | 161 |
| Balance as of December 31, 2017 | (529) | (6) | (144) | — | (679) |
| Cumulative effect of change in accounting principle, net of tax[(1)] | — | — | (9) | — | (9) |
| Foreign currency translation adjustments | (141) | — | — | — | (141) |
| Unrealized gains (losses) | — | 61 | (556) | — | (495) |
| Reclassification adjustments to income | — | 262 | 365 | — | 627 |
| Other | — | — | — | (2) | (2) |
| Income taxes | — | (76) | 6 | — | (70) |
| Balance as of December 31, 2018 | $ (670) | $ 241 | $ (338) | $ (2) | $ (769) |

(1) See Note 1, Summary of significant accounting policies, for additional information regarding the adoption on January 1, 2018, of the new accounting standard related to the classification and measurement of financial instruments and the related cumulative effect from the change in accounting principle.

With respect to the table above, income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges were a $21 million expense and $55 million expense in 2018, a $68 million expense and $226 million benefit in 2017 and a $68 million benefit and $46 million expense in 2016, respectively. Income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities were a $9 million benefit and $3 million expense for 2018, a $9 million expense and $8 million benefit in 2017 and a $9 million benefit and $11 million expense in 2016, respectively.

Reclassifications out of AOCI and into earnings were as follows (in millions):

| | Years ended December 31, | | | |
|---|---|---|---|---|
| Components of AOCI | 2018 | 2017 | 2016 | Consolidated Statements of Income locations |
| Cash flow hedges: | | | | |
| Foreign currency contract (losses) gains | $(21) | $65 | $308 | Product sales |
| Cross-currency swap contract (losses) gains | (241) | 574 | (446) | Interest and other income, net |
| Forward interest rate contract losses | — | (1) | (1) | Interest expense, net |
| | (262) | 638 | (139) | Income before income taxes |
| | 55 | (226) | 46 | Provision for income taxes |
| | $(207) | $412 | $(93) | Net income |
| Available-for-sale securities: | | | | |
| Net realized losses | $(365) | $(41) | $(61) | Interest and other income, net |
| | 3 | (8) | 11 | Provision for income taxes |
| | $(362) | $(49) | $(50) | Net income |

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2018 and 2017, no shares of preferred stock were issued or outstanding.

18. Fair value measurement

To estimate the fair value of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access

Level 2—Valuations for which all significant inputs are observable either directly or indirectly—other than Level 1 inputs

Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair values of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis were as follows (in millions):

| Fair value measurement as of December 31, 2018, using: | Quoted prices in active markets for identical assets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) | Total |
|---|---|---|---|---|
| Assets: | | | | |
| Interest-bearing securities: | | | | |
| U.S. Treasury notes | $ 2,663 | $ — | $ — | $2,663 |
| U.S. Treasury bills | 8,191 | — | — | 8,191 |
| Other government-related debt securities: | | | | |
| U.S. | — | 110 | — | 110 |
| Foreign and other | — | 932 | — | 932 |
| Corporate debt securities: | | | | |
| Financial | — | 2,697 | — | 2,697 |
| Industrial | — | 2,504 | — | 2,504 |
| Other | — | 562 | — | 562 |
| Residential-mortgage-backed securities | — | 1,422 | — | 1,422 |
| Other mortgage- and asset-backed securities | — | 469 | — | 469 |
| Money market mutual funds | 5,659 | — | — | 5,659 |
| Other short-term interest-bearing securities | — | 3,515 | — | 3,515 |
| Equity securities | 176 | — | — | 176 |
| Derivatives: | | | | |
| Foreign currency contracts | — | 182 | — | 182 |
| Cross-currency swap contracts | — | 170 | — | 170 |
| Interest rate swap contracts | — | 56 | — | 56 |
| Total assets | $ 16,689 | $ 12,619 | $ — | $29,308 |
| Liabilities: | | | | |
| Derivatives: | | | | |
| Foreign currency contracts | $ — | $ 26 | $ — | $26 |
| Cross-currency swap contracts | — | 401 | — | 401 |
| Interest rate swap contracts | — | 149 | — | 149 |
| Contingent consideration obligations | — | — | 72 | 72 |
| Total liabilities | $ — | $ 576 | $ 72 | $648 |

| Fair value measurement as of December 31, 2017, using: | Quoted prices in active markets for identical assets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) | Total |
|---|---|---|---|---|
| Assets: | | | | |
| Interest-bearing securities: | | | | |
| U.S. Treasury notes | $ 8,242 | $ — | $ — | $8,242 |
| Other government-related debt securities: | | | | |
| U.S. | — | 223 | — | 223 |
| Foreign and other | — | 2,422 | — | 2,422 |
| Corporate debt securities: | | | | |
| Financial | — | 10,072 | — | 10,072 |
| Industrial | — | 9,670 | — | 9,670 |
| Other | — | 1,390 | — | 1,390 |
| Residential-mortgage-backed securities | — | 2,168 | — | 2,168 |
| Other mortgage- and asset-backed securities | — | 2,297 | — | 2,297 |
| Money market mutual funds | 3,245 | — | — | 3,245 |
| Other short-term interest-bearing securities | — | 1,440 | — | 1,440 |
| Equity securities | 149 | — | — | 149 |
| Derivatives: | | | | |
| Foreign currency contracts | — | 6 | — | 6 |
| Cross-currency swap contracts | — | 270 | — | 270 |
| Interest rate swap contracts | — | 10 | — | 10 |
| Total assets | $ 11,636 | $ 29,968 | $ — | $41,604 |
| Liabilities: | | | | |
| Derivatives: | | | | |
| Foreign currency contracts | $ — | $ 204 | $ — | $204 |
| Cross-currency swap contracts | — | 220 | — | 220 |
| Interest rate swap contracts | — | 61 | — | 61 |
| Contingent consideration obligations | — | — | 69 | 69 |
| Total liabilities | $ — | $ 485 | $ 69 | $554 |

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity securities are based on quoted market prices in active markets, with no valuation adjustment.

Most of our other government-related and corporate debt securities are investment grade and have maturity dates of five years or less from the balance sheet date. Our other government-related debt securities portfolio is composed of securities with weighted-average credit ratings of A– or equivalent by Standard & Poor's Financial Services LLC (S&P), Moody's Investors Service, Inc. (Moody's) or Fitch Ratings, Inc. (Fitch); and our corporate debt securities portfolio has weighted-average credit ratings of A– or equivalent by Fitch and BBB + or equivalent by S&P or Moody's. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

Our residential-mortgage-, other-mortgage- and asset-backed-securities portfolio is composed entirely of senior tranches with credit ratings of AAA by S&P, Moody's or Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry-standard valuation models, including both income- and market-based approaches, for which all significant

inputs are observable either directly or indirectly to estimate fair value. The inputs include reported trades of and broker-dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment or default projections based on historical data; and other observable inputs.

We value our other short-term interest-bearing securities at amortized cost, which approximates fair value given their near-term maturity dates.

Derivatives

All of our foreign currency forward and option derivative contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. These inputs, where applicable, are at commonly quoted intervals. See Note 19, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 19, Derivative instruments.

Our interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by using an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR, swap rates and obligor credit default swap rates. See Note 19, Derivative instruments.

Contingent consideration obligations

As a result of our business acquisitions, we have incurred contingent consideration obligations, as discussed below. The contingent consideration obligations are recorded at their fair values by using probability-adjusted discounted cash flows, and we revalue these obligations each reporting period until the related contingencies have been resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to licensing rights and product candidates acquired in business combinations, and are reviewed quarterly by management in our R&D and commercial sales organizations. These inputs include, as applicable, estimated probabilities and the timing of achieving specified regulatory and commercial milestones as well as estimated annual sales. Significant changes that increase or decrease the probabilities of achieving the related regulatory and commercial events or that shorten or lengthen the time required to achieve such events or that increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of the obligations, as applicable. Changes in the fair values of contingent consideration obligations are recognized in Other operating expenses in the Consolidated Statements of Income.

Changes in the carrying amounts of contingent consideration obligations were as follows (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Beginning balance | $69 | $179 | $188 |
| Addition from K-A acquisition | 45 | — | — |
| Net changes in valuations | (42) | (110) | (9) |
| Ending balance | $72 | $69 | $179 |

As a result of our acquisition of K-A in 2018, we are obligated to make single-digit royalty payments to Kirin contingent upon sales of brodalumab. See Note 3, Business combinations.

As a result of our acquisition of Dezima in 2015, we are obligated to pay its former shareholders up to $1.25 billion of additional consideration contingent upon achieving certain development and sales-related milestones and low single-digit royalties on net product sales above a certain threshold for AMG 899, an IPR&D asset. The fair values of the contingent consideration obligations had an aggregate value of $110 million at acquisition. During 2017, we decided to discontinue the internal development of AMG 899 and accordingly, reduced from $116 million to zero the related contingent consideration liabilities and recognized an impairment charge of $400 million on the IPR&D asset

in Other operating expenses in the Consolidated Statements of Income. The remeasurement of these liabilities and the impairment charge are included in Other items, net, in the Consolidated Statements of Cash Flows.

As a result of our acquisition of BioVex Group Inc. in 2011, we are obligated to pay its former shareholders up to $325 million upon achieving separate regulatory and sales-related milestones with regard to IMLYGIC® (talimogene laherparepvec) if certain sales thresholds are met within specified periods of time.

During the years ended December 31, 2018 and 2017, there were no transfers of assets or liabilities between fair value measurement levels. During the years ended December 31, 2018 and 2017, there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis, except with respect to the IPR&D asset discussed above and in Note 14, Goodwill and other intangible assets.

Summary of the fair values of other financial instruments

Cash equivalents

The fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of December 31, 2018 and 2017, the aggregate fair values of our borrowings were $35.0 billion and $38.6 billion, respectively, and the carrying values were $33.9 billion and $35.3 billion, respectively.

19. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

During 2018, we adopted early a new accounting standard that amends the accounting and reporting of hedging activities. Certain required disclosures have been made on a prospective basis in accordance with the guidance of the standard. See Note 1, Summary of significant accounting policies.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates associated primarily with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are offset partially by corresponding increases and decreases in the cash flows from our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations with regard to our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of December 31, 2018, 2017 and 2016, we had foreign currency forward contracts with notional amounts of $4.5 billion, $4.6 billion and $3.4 billion, respectively, and foreign currency option contracts with notional amounts of $21 million, $74 million and $608 million, respectively. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Consolidated Balance Sheets, and we reclassify them to Product sales in the Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term debt denominated in foreign currencies, we enter into cross-currency swap contracts. Under the terms of such contracts, we paid euros, pounds sterling and Swiss francs and received U.S. dollars for the notional amounts at the inception of the contracts; and based on these notional amounts, we exchange interest payments at fixed rates over the lives of the contracts by paying U.S. dollars and receiving euros, pounds sterling and Swiss francs. In addition, we will pay U.S. dollars to and receive euros, pounds sterling and Swiss francs from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged debt, thereby effectively converting the interest payments and principal repayment on the debt from euros, pounds sterling and Swiss francs to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges.

Accordingly, the unrealized gains and losses on these contracts are reported in AOCI in the Consolidated Balance Sheets and

reclassified to Interest and other income, net, in the Consolidated Statements of Income in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of December 31, 2018, were as follows (notional amounts in millions):

| | Foreign currency | | U.S. dollars | |
|---|---|---|---|---|
| Hedged notes | Notional amounts | Interest rates | Notional amounts | Interest rates |
| 2.125% 2019 euro Notes | € 675 | 2.1 % | $864 | 2.6 % |
| 1.25% 2022 euro Notes | € 1,250 | 1.3 % | $1,388 | 3.2 % |
| 0.41 % 2023 Swiss franc Bonds | CHF700 | 0.4 % | $704 | 3.4 % |
| 2.00% 2026 euro Notes | € 750 | 2.0 % | $833 | 3.9 % |
| 5.50% 2026 pound sterling Notes | £ 475 | 5.5 % | $747 | 6.0 % |
| 4.00% 2029 pound sterling Notes | £ 700 | 4.0 % | $1,111 | 4.5 % |

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Consolidated Balance Sheets and are amortized into Interest expense, net, in the Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the year ended December 31, 2018, and amounts expected to be recognized during the subsequent 12 months are not material.

The unrealized gains and losses recognized in AOCI for our derivative instruments designated as cash flow hedges were as follows (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| Derivatives in cash flow hedging relationships | 2018 | 2017 | 2016 |
| Foreign currency contracts | $348 | $(402) | $115 |
| Cross-currency swap contracts | (287) | 581 | (281) |
| Forward interest rate contracts | — | 13 | (10) |
| Total unrealized gains (losses) | $61 | $192 | $(176) |

The locations in the Consolidated Statements of Income and the gains and losses reclassified out of AOCI and into earnings for our derivative instruments designated as cash flow hedges were as follows (in millions):

| | | Years ended December 31, | | |
|---|---|---|---|---|
| Derivatives in cash flow hedging relationships | Consolidated Statements of Income locations | 2018 | 2017 | 2016 |
| Foreign currency contracts | Product sales | $(21) | $65 | $308 |
| Cross-currency swap contracts | Interest and other income, net | (241) | 574 | (446) |
| Forward interest rate contracts | Interest expense, net | — | (1) | (1) |
| Total realized (losses) gains | | $(262) | $638 | $(139) |

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of December 31, 2018, the amount expected to be reclassified out of AOCI and into earnings during the next 12 months is $110 million of net losses on our foreign currency and cross-currency swap contracts.

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified for and were designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate LIBOR-based coupons over the terms of the related hedge contracts. During the year ended December 31, 2018, we entered into $1.5 billion of interest rate swaps. As of December 31, 2018 and 2017, we had interest rate swap contracts with aggregate notional amounts of $10.95 billion and $9.45 billion, respectively, that hedge certain of our long-term debt issuances. See Note 16, Financing arrangements—Interest rate swaps.

For interest rate swap contracts that qualify for and are designated as fair value hedges, we recognize in Interest expense, net, in the Consolidated Statements of Income, the unrealized gain or loss on the derivative resulting from the change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. If a hedging relationship involving an interest rate swap contract is terminated, the gain or loss realized on contract termination is recorded as an adjustment to the carrying value of the debt and amortized into Interest expense, net, over the remaining life of the previously hedged debt.

Net unrealized gains and losses on our outstanding interest rate swap contracts were as follows (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| Derivatives in fair value hedging relationships | 2018 | 2017 | 2016 |
| Net unrealized losses recognized on interest rate swap contracts | $(42) | $(85) | $(34) |
| Net unrealized gains recognized on related hedged debt | $42 | $85 | $34 |

The hedged liabilities and related cumulative-basis adjustments for fair value hedges of those liabilities were recorded in the Consolidated Balance Sheets as follows (in millions):

| | Carrying amounts of hedged liabilities[1] | | Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2] | |
|---|---|---|---|---|
| | December 31, | | December 31, | |
| Consolidated Balance Sheets locations | 2018 | 2017 | 2018 | 2017 |
| Current portion of long-term debt | $2,396 | $500 | $(3) | $23 |
| Long-term debt | $9,361 | $10,516 | $(50) | $(11) |

(1) Current portion of long-term debt includes $1.0 billion and $500 million of carrying value with discontinued hedging relationships as of December 31, 2018 and 2017, respectively. Long-term debt includes $137 million and $1.1 billion of carrying value with discontinued hedging relationships as of December 31, 2018 and 2017, respectively.

(2) Current portion of long-term debt includes $3 million and $23 million of hedging adjustments on discontinued hedging relationships as of December 31, 2018 and 2017, respectively. Long-term debt includes $37 million and $40 million of hedging adjustments on discontinued hedging relationships as of December 31, 2018 and 2017, respectively.

The following table summarizes the amounts recorded in income and expense line items and the effects thereon from fair value and cash flow hedging, including discontinued hedging relationships (in millions):

| | Year ended December 31, 2018 | | |
|---|---|---|---|
| | Product sales | Interest and other income, net | Interest (expense), net |
| Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income | $22,533 | $ 674 | $ (1,392) |
| The effects of cash flow and fair value hedging: | | | |
| Losses on cash flow hedging relationships reclassified out of AOCI: | | | |
| Foreign currency contracts | $(21) | | |
| Cross-currency swap contracts | | $ (241) | |
| Gains (losses) on fair value hedging relationships—interest rate swap agreements: | | | |
| Hedged items[1] | | | $ 65 |
| Derivatives designated as hedging instruments | | | $ (42) |

[1] The amounts include benefits of $23 million related to the amortization of the cumulative amount of fair value hedging adjustments included in the carrying amount of the hedged debt for discontinued hedging relationships for the year ended December 31, 2018.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. These exposures are hedged on a month-to-month basis. As of December 31, 2018, 2017 and 2016, the total notional amounts of these foreign currency forward contracts were $737 million, $757 million and $666 million, respectively. The fair values of these derivatives as of December 31, 2018 and 2017, were not material.

The location in the Consolidated Statements of Income and the amounts of gains (losses) recognized in earnings for our derivative instruments not designated as hedging instruments were as follows (in millions):

| | | Years ended December 31, | | |
|---|---|---|---|---|
| Derivatives not designated as hedging instruments | Consolidated Statements of Income location | 2018 | 2017 | 2016 |
| Foreign currency contracts | Interest and other income, net | $34 | $ 24 | $(56) |

The fair values of derivatives included in the Consolidated Balance Sheets were as follows (in millions):

| December 31, 2018 | Derivative assets Consolidated Balance Sheets locations | Fair values | Derivative liabilities Consolidated Balance Sheets locations | Fair values |
|---|---|---|---|---|
| Derivatives designated as hedging instruments: | | | | |
| Foreign currency contracts | Other current assets/ Other assets | $ 181 | Accrued liabilities/ Other noncurrent liabilities | $ 26 |
| Cross-currency swap contracts | Other current assets/ Other assets | 170 | Accrued liabilities/ Other noncurrent liabilities | 401 |
| Interest rate swap contracts | Other current assets/ Other assets | 56 | Accrued liabilities/ Other noncurrent liabilities | 149 |
| Total derivatives designated as hedging instruments | | 407 | | 576 |
| Derivatives not designated as hedging instruments: | | | | |
| Foreign currency contracts | Other current assets | 1 | Accrued liabilities | — |
| Total derivatives not designated as hedging instruments | | 1 | | — |
| Total derivatives | | $ 408 | | $ 576 |

| December 31, 2017 | Derivative assets Consolidated Balance Sheets locations | Fair values | Derivative liabilities Consolidated Balance Sheets locations | Fair values |
|---|---|---|---|---|
| Derivatives designated as hedging instruments: | | | | |
| Foreign currency contracts | Other current assets/ Other assets | $ 6 | Accrued liabilities/ Other noncurrent liabilities | $ 204 |
| Cross-currency swap contracts | Other current assets/ Other assets | 270 | Accrued liabilities/ Other noncurrent liabilities | 220 |
| Interest rate swap contracts | Other current assets/ Other assets | 10 | Accrued liabilities/ Other noncurrent liabilities | 61 |
| Total derivatives designated as hedging instruments | | $ 286 | | $ 485 |

Our derivative contracts that were in liability positions as of December 31, 2018, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our, or the surviving entity's, creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right but not the obligation to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts are included within Net cash provided by operating activities in the Consolidated Statements of Cash Flows.

20. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See Part I, Item 1A. Risk Factors—Our business may be affected by litigation and government investigations. We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing in which we could incur a liability, our opponents seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters described in this filing in which we could incur a liability have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. In addition, while some of the matters described in this filing do not present circumstances in which we could incur a liability (such as some matters involving our claims that others have infringed our patents and in which such others have not asserted counterclaims against us), such matters nevertheless have the potential to significantly impact our business. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain recent developments concerning our legal proceedings and other matters are discussed below:

Sensipar® (cinacalcet) Abbreviated New Drug Application (ANDA) Patent Litigation

Amgen Inc. v. Aurobindo Pharma Ltd. et al.

Beginning in September 2016, Amgen filed 14 separate lawsuits in the U.S. District Court for the District of Delaware (the Delaware District Court) for infringement of our U.S. Patent No. 9,375,405 (the ’405 Patent) against a number of manufacturers of purported generic versions of our Sensipar® product. In February 2017, the Delaware District Court consolidated these 14 lawsuits into a single case, Amgen Inc. v. Aurobindo Pharma Ltd. et al. The ’405 Patent is entitled “Rapid Dissolution Formulation of a Calcium Receptor-Active Compound” and expires in 2026. All defendants responding to the complaint denied infringement and sought judgment that the ’405 Patent is invalid and/or not infringed. Between September and November of 2017, Amgen filed, and the Delaware District Court signed, stipulated dismissals of the lawsuit against Micro Labs Ltd. and Micro Labs USA, Inc., and the lawsuit against Apotex Inc. and Apotex Corp. (collectively, Apotex), as well as consent judgments filed by Amgen and each of (1) Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, Sun), (2) Ajanta Pharma Limited and Ajanta Pharma USA, Inc., (3) Hetero USA Inc., Hetero Labs Ltd. and Hetero Labs Ltd. Unit V and (4) Breckenridge Pharmaceutical, Inc. (Breckenridge). Each consent judgment stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of the respective defendant’s cinacalcet product during the term of the ’405 Patent unless specifically authorized pursuant to the confidential settlement agreement.

In June 2017, Amgen filed four additional lawsuits in the Delaware District Court for infringement of the ’405 Patent against additional defendants. These defendants also responded to the complaint denying infringement and seeking a declaration of noninfringement and invalidity of the ’405 Patent. One of these lawsuits was subsequently consolidated into Amgen Inc. v. Aurobindo Pharma Ltd. et al. and the remaining three of these lawsuits were consolidated into a separate single case, Amgen Inc. v. Alkem et al. (see below).

On March 5, 2018, the Delaware District Court commenced trial on the infringement claims and defenses in the Amgen Inc. v. Aurobindo Pharma Ltd. et al. consolidated lawsuit against the defendants that remained in the lawsuit, collectively consisting of (1) Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, Aurobindo), (2)

Watson Laboratories, Inc. and Actavis Pharma, Inc. (collectively, Watson), (3) Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Private Limited, (4) Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, Zydus) and (5) Piramal Healthcare UK Limited (Piramal).

Just prior to trial, the Delaware District Court signed consent judgments filed by Amgen and each of Cipla Limited and Cipla USA, Inc. (collectively, Cipla) and Strides Pharma Global PTE Limited and Strides Pharma, Inc. (collectively, Strides), and in

March 2018 the Delaware District Court signed a consent judgment filed by Amgen and Aurobindo. In each consent judgment, the parties stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of the applicable defendant’s cinacalcet product during the term of the ’405 Patent unless specifically authorized pursuant to the applicable confidential settlement agreement. Just prior to trial, the Delaware District Court also entered orders dismissing each of Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, Dr. Reddy’s), and Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan), on stipulations between Amgen and such parties, respectively, subject to the terms of confidential settlement agreements.

On July 27, 2018, the Delaware District Court issued a trial order finding on the infringement claims and defenses in the Amgen Inc. v. Aurobindo Pharma Ltd. et al. consolidated lawsuit that Zydus infringes the ’405 Patent and that Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal), Piramal and Watson do not infringe the ’405 Patent. On August 24, 2018, the Delaware District Court issued an order dismissing, without prejudice, the invalidity counterclaims of Amneal, Piramal and Watson and entered judgment of noninfringement of the ’405 Patent in favor of Amneal, Piramal and Watson. On September 20, 2018, Amgen filed a notice of appeal to the Federal Circuit Court. On October 9, 2018, the Delaware District Court dismissed, without prejudice, the invalidity counterclaims of Zydus and entered judgment of infringement of the ’405 Patent by Zydus in favor of Amgen, including an order that the effective date of the U.S. Food and Drug Administration (FDA) approval of Zydus’ generic version of Sensipar® shall be no earlier than the expiry date of our ’405 Patent. On October 11, 2018, Zydus filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) and on October 24, 2018, the Federal Circuit Court consolidated the appeals of Zydus and Amgen.

In December 2018, the FDA approved Watson’s generic version of Sensipar® and Watson’s parent company, Teva Pharmaceutical Industries Ltd. (Teva), began selling its product at-risk notwithstanding that the appeals were pending at the Federal Circuit Court. On January 2, 2019, Amgen, Watson and Teva entered into a settlement agreement in which Teva agreed to stop selling its generic product until the mid-year 2021, or earlier under certain circumstances, and to pay Amgen an undisclosed amount. On January 9, 2019, Watson and Amgen filed a motion asking the Delaware District Court to vacate its final judgment of noninfringement as to Watson and to enter a proposed consent judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the making, having made, using, selling, offering to sell, or distributing Watson’s cinacalcet product in the United States, or importing Watson’s cinacalcet product into the United States, consistent with the confidential settlement agreement. On January 11, 2019, the Federal Circuit Court stayed the pending appeal as to Watson in order for the Delaware District Court to rule on the motion of Watson and Amgen. On January 18, 2019 and January 23, 2019, respectively, Cipla and Sun filed oppositions to the motion of Watson and Amgen.

On January 8, 2019, Cipla filed a separate lawsuit in the Delaware District Court against Amgen seeking a declaration that provisions of its settlement agreement with Amgen have been triggered by Teva’s at-risk launch of Watson’s generic version of Sensipar®, giving Cipla a right to market its own generic version under its settlement agreement. Cipla’s complaint also alleges antitrust violations by Amgen. The portions of the complaint covering Cipla’s settlement agreement were filed with the court under seal and remain confidential.

Amgen Inc. v. Alkem et al.

As stated above, Amgen filed four lawsuits in June 2017 for infringement of the ’405 Patent. In December 2017, the lawsuits filed against (1) Alkem Laboratories Ltd. (Alkem), (2) Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, Lupin) and (3) Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, Macleods) were consolidated into a separate single case, Amgen Inc. v. Alkem et al. In each of those three lawsuits, all defendants responded to the complaint denying infringement and seeking a declaration of noninfringement and invalidity of the ’405 Patent; Macleods’ response also included a counterclaim alleging sham litigation in violation of the Sherman Antitrust Act, which Amgen has denied and which the Delaware District Court stayed pending resolution of the patent claims.

In March 2018, the Delaware District Court signed a consent judgment filed by Amgen and Macleods in which the parties stipulated to an entry of judgment of infringement and validity of the ’405 Patent and an injunction prohibiting the manufacture, use, sale, offer to sell, importation of, or distribution into the United States of Macleods’ cinacalcet

product during the term of the ’405 Patent unless specifically authorized pursuant to the confidential settlement agreement. In April 2018, the Delaware District Court also entered orders respectively dismissing Lupin and Alkem on stipulations between the parties, subject to the terms of confidential settlement agreements.

Other Sensipar® ANDA Patent Litigation

In December 2017, Amgen filed four additional lawsuits in the Delaware District Court for infringement of the ’405 Patent against (1) Watson, (2) Teva Pharmaceuticals, USA, Inc., (3) Barr Laboratories, Inc. and (4) Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. These lawsuits were distinct from the suits consolidated into Amgen Inc. v. Aurobindo Pharma Ltd. et al., and all four additional suits were subsequently dismissed by agreement between Amgen and the respective defendants.

In June 2018, Amgen filed a lawsuit in the Delaware District Court against Accord Healthcare, Inc. (Accord) and Intas Pharmaceuticals Ltd. (Intas) for infringement of the ’405 Patent. Amgen seeks an order making any FDA approval of these defendants’ generic version of Sensipar® effective no earlier than the expiration of the ’405 Patent. On September 18, 2018, Accord denied infringement of the ’405 Patent and alleged that the patent is invalid. On September 20, 2018, Intas was dismissed from the Delaware District Court lawsuit without prejudice by joint stipulation of the parties. On February 1, 2019, Accord filed a motion for summary judgment of noninfringement. Trial is scheduled to begin June 15, 2020.

On September 7, 2018, Amgen filed a lawsuit in the Delaware District Court for infringement of the ’405 Patent against Emcure Pharmaceuticals Ltd., Heritage Pharmaceuticals Inc. and Heritage Pharma Labs Inc. In December 2018, the Delaware District Court entered an order dismissing all defendants on a stipulation between the parties, subject to the terms of a confidential settlement agreement.

KYPROLIS® (carfilzomib) ANDA Patent Litigation

Beginning in October 2016, our subsidiary Onyx Therapeutics, Inc. (Onyx Therapeutics), filed four separate lawsuits in the Delaware District Court against: (1) Cipla, (2) Sagent Pharmaceuticals, Inc. (Sagent), (3) Breckenridge and (4) Fresenius Kabi, USA LLC, Fresenius Kabi USA, Inc., Fresenius Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited, each for infringing U.S. Patent Nos. 7,232,818 (the ’818 Patent), 7,417,042 (the ’042 Patent), 7,491,704 (the ’704 Patent), 7,737,112 (the ’112 Patent), 8,129,346 (the ’346 Patent), 8,207,125 (the ’125 Patent), 8,207,126 (the ’126 Patent), 8,207,127 (the ’127 Patent) and 8,207,297 (the ’297 Patent). By joint stipulation of the parties, Fresenius Pharmaceuticals Holding, Inc. and Fresenius Kabi Oncology Limited were subsequently dismissed from the lawsuit against them. In October and November 2016, Onyx Therapeutics also filed four separate lawsuits in the Delaware District Court against: (1) MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (collectively, MSN), (2) Dr. Reddy’s, (3) Qilu Pharma, Inc. and Qilu Pharmaceutical Co. Ltd. (collectively, Qilu) and (4) Apotex, each for infringing the ’112 Patent; and a separate lawsuit against InnoPharma, Inc. (InnoPharma) for infringement of the ’042, ’112 and ’297 Patents. In April 2017, Onyx Therapeutics filed a separate lawsuit in the Delaware District Court against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. for infringement of the ’818, ’042, ’704, ’112, ’346, ’125, ’126, ’127 and ’297 Patents. The Delaware District Court has consolidated these ten lawsuits for purposes of discovery into a single case, Onyx Therapeutics, Inc. v. Cipla Limited., et al.

In August 2017, Onyx Therapeutics filed additional lawsuits in the Delaware District Court against InnoPharma for infringement of the ’818, ’704, ’346, ’125, ’126 and ’127 Patents; and against Apotex and Qilu for infringement of the ’818, ’042, ’704, ’346, ’125, ’126, ’127 and ’297 Patents. On September 14, 2017, the Delaware District Court consolidated these three additional lawsuits for purposes of discovery into the existing consolidated case.

In September 2017, by joint stipulation of the parties, Teva Pharmaceutical Industries Ltd. was dismissed from the suit against it, leaving Teva Pharmaceuticals USA, Inc., as the remaining defendant in that litigation.

In November 2017, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Aurobindo Pharma USA, Inc. (Aurobindo) for infringement of the ’818, ’042, ’704, ’112, ’346, ’125, ’126, ’127 and ’297 Patents. In December 2017, Onyx Therapeutics filed additional lawsuits in the Delaware District Court against Dr. Reddy’s for infringement of the ’818, ’042, ’704, ’346, ’125, ’126, ’127 and ’297 Patents, and against MSN for infringement of the ’112 Patent. In January 2018, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Apotex for infringement of the ’818, ’042, ’704, ’112, ’346, ’125, ’126, ’127 and ’297 Patents.

In February 2018, Qilu and Teva Pharmaceuticals USA, Inc. were each dismissed from the applicable lawsuits by joint stipulation of the parties. On February 7, 2018, the Delaware District Court also consolidated for purposes of discovery the lawsuit against Aurobindo into the existing consolidated case, Onyx Therapeutics, Inc. v. Cipla Limited, et al. On March 20, 2018, the Delaware District Court entered a stipulation between the parties providing Aurobindo a covenant not to sue on the ’818,’704,’346 and ’297 Patents.

On February 15, 2018, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Breckenridge for patent infringement, and subsequently amended the complaint on March 9, 2018 to assert infringement of the ’042, ’112, ’125, ’126 and ’127 Patents. On April 20, 2018, Onyx Therapeutics filed a lawsuit in the Delaware District Court against Cipla for patent infringement of the ’042, ’112, ’125, ’126 and ’127 Patents.

The lawsuits filed between 2016-2018 are based on ANDAs that seek approval to market generic versions of KYPROLIS® before expiration of the asserted patent or patents. In each lawsuit, Onyx Therapeutics seeks an order of the Delaware District Court making any FDA approval of the respective defendant's ANDA effective no earlier than the expiration of the applicable patents. Responses to the complaints have been filed by all defendants alleging invalidity and, in certain instances, noninfringement of the patents.

During April 2018, the Delaware District Court entered orders on stipulations between Onyx Therapeutics and each of Apotex, Dr. Reddy's and Sagent, respectively, that each defendant infringes the '042, '112, '125, '126 and '127 Patents, and that Onyx Therapeutics will not assert patent infringement of the '818, '704, '346 and '297 Patents against certain of the respective defendants' ANDA applications and products. During May, June and July of 2018, the Delaware District Court entered orders on stipulations between Onyx Therapeutics and each of Fresenius Kabi, USA LLC and Fresenius Kabi USA, Inc. (collectively, Fresenius), Breckenridge, Aurobindo, Cipla and Innopharma, respectively, that each defendant infringes the '042, '112, '125, '126 and '127 Patents. Onyx Therapeutics had previously provided those defendants a covenant that it would not assert patent infringement of the '818,'704,'346 and '297 Patents against certain of the respective defendants' ANDA applications and products. On June 4, 2018, the Delaware District Court also entered an order on a stipulation between Onyx Therapeutics and MSN that MSN infringes the '112 Patent.

In December 2018, Apotex, Dr. Reddy's, Fresenius, InnoPharma, Sagent, Breckenridge, Aurobindo and Cipla amended their responses to the complaints to add the defense of unclean hands and to seek declarations of unenforceability of the asserted patents based on allegations of inequitable conduct. In January 2019, MSN amended its responses to the complaints to add the defense of unclean hands. Trial in the consolidated case is scheduled to commence on May 6, 2019.

On January 11, 2019, Onyx Therapeutics filed a separate lawsuit in the Delaware District Court against Breckenridge for infringing the '042, '112 and '125 Patents in connection with its ANDA that seeks approval to market generic versions of KYPROLIS® before expiration of those patents. Onyx Therapeutics seeks an order from the Delaware District Court making any FDA approval of Breckenridge's ANDA effective no earlier than the expiration of the applicable patents.

Sandoz ENBREL (etanercept) Patent Litigation

On February 26, 2016, two affiliates of Amgen Inc. (Immunex Corporation and Amgen Manufacturing, Limited (AML) (collectively, Amgen)), along with Hoffmann-La Roche Inc. (Roche), filed a lawsuit in the U.S. District Court for the District of New Jersey (the New Jersey District Court) against Sandoz Inc., Sandoz International GmbH and Sandoz GmbH (collectively, Sandoz). This lawsuit stems from Sandoz's submission of an application for FDA licensure of an etanercept product as biosimilar to Amgen's ENBREL. Amgen and Roche have asserted infringement of five patents: U.S. Patent Nos. 8,063,182 (the '182 Patent); 8,163,522 (the '522 Patent); 7,915,225; 8,119,605; and 8,722,631 (the '631 Patent). By their complaint, Amgen and Roche seek an injunction to prohibit Sandoz from commercializing its biosimilar etanercept product in the United States prior to the expiry of such patents. Responses have been filed by all Sandoz defendants denying infringement and/or asserting that the patents at issue are invalid.

On August 11, 2016, and subject to the terms of a confidential stipulation, the New Jersey District Court entered a preliminary injunction prohibiting Sandoz from making, using, importing, selling or offering for sale Sandoz's etanercept product. On August 30, 2016, the FDA approved Sandoz's Erelzi™, a biosimilar to ENBREL.

On September 14, 2017, Amgen filed a motion for summary judgment that Sandoz infringed claim 1 of the '631 Patent and, on October 23, 2017, Sandoz filed its brief in opposition to the motion.

On September 10, 2018, the New Jersey District Court entered an order that the making, using, offering to sell or selling in the United States, or the importation into the United States by Sandoz of Sandoz's biosimilar etanercept product infringes the '182 Patent and the '522 Patent. The New Jersey District Court held a bench trial from September 11, 2018, to September 25, 2018, focusing on Sandoz's challenges to the validity of these patents. Closing arguments were heard on November 19, 2018, and the parties await the court's verdict.

NEUPOGEN® (filgrastim) / Neulasta® (pegfilgrastim) Patent Litigation

Adello NEUPOGEN® Patent Litigation

On March 8, 2018, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the New Jersey District Court against Adello Biologics, LLC (Adello). This lawsuit stems from Adello's submission of an application for FDA licensure of a filgrastim product as biosimilar to Amgen's NEUPOGEN®. Amgen has asserted infringement of 17 of our patents. Amgen seeks an injunction to prohibit Adello from commercializing its biosimilar filgrastim product in the United States prior to the expiry of these patents. On May 17, 2018, Adello responded to Amgen's lawsuit for patent infringement, denying infringement and seeking judgment that the patents-in-suit are invalid and not infringed.

On October 3, 2018, Amgen filed a first amended complaint in the New Jersey District Court adding as defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. (collectively, Amneal) and reducing the number of patents-in-suit from 17 to 4: U.S. Patent Nos. 8,940,878 (the ’878 Patent); 8,952,138 (the ’138 Patent); 9,643,997 (the ’997 Patent); and 9,856,287 (the ’287 Patent). On October 17, 2018, Adello responded to the first amended complaint, seeking judgment that our patents-in-suit are not infringed by Adello’s biosimilar filgrastim product and that our patents are invalid. On December 5, 2018, Amneal filed a motion to dismiss the claims against it for failure to state a claim and for lack of subject-matter jurisdiction.

Apotex NEUPOGEN® / Neulasta® Patent Litigation

On August 7, 2018, Amgen filed a lawsuit in the U.S. District Court for the Southern District of Florida against Apotex for infringement of the ’287 Patent in accordance with the patent provisions of the Biologics Price Competition and Innovation Act (BPCIA). This lawsuit stems from Apotex’s submissions of applications for FDA licensure of a pegfilgrastim product as biosimilar to Amgen’s Neulasta® and a filgrastim product as biosimilar to Amgen’s NEUPOGEN®. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Apotex from infringing the ’287 Patent. On December 10, 2018, Apotex filed a motion to dismiss the complaint for failure to state a claim. A hearing on the motion to dismiss is scheduled for March 15, 2019.

On October 1, 2018, Apotex and Adello Biologics, LLC filed a petition in the U.S. Patent and Trademark Office requesting that the Patent Trial and Appeal Board (PTAB) institute post grant review proceedings on the ’287 Patent. On January 23, 2019, Amgen filed a patent owner’s preliminary response.

On February 17, 2017, the PTAB of the U.S. Patent and Trademark Office granted Apotex’s petition to institute an inter partes review (IPR) of the ’138 Patent, challenging claims of the ’138 Patent as unpatentable. On May 22, 2017, Amgen filed its response and oral argument was held before the PTAB on December 13, 2017. The PTAB issued a final decision on the IPR of the ’138 Patent holding all but one claim of the ’138 Patent as unpatentable. On March 16, 2018, Apotex filed a request for rehearing on the PTAB’s finding that this one claim is patentable.

Coherus Neulasta® Patent Litigation

On May 10, 2017, Amgen filed a lawsuit in the Delaware District Court against Coherus BioSciences, Inc. (Coherus) for infringement of our U.S. Patent No. 8,273,707 (the ’707 Patent). This lawsuit stems from Coherus’ submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen’s Neulasta® under the BPCIA. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Coherus from infringing the ’707 Patent. On March 26, 2018, the Delaware District Court granted Coherus’ motion to dismiss Amgen’s complaint for failure to state a claim and final judgment was entered dismissing Amgen’s complaint on April 18, 2018. On May 17, 2018, Amgen appealed the judgment to the Federal Circuit Court. On November 2, 2018, the FDA approved Coherus’ UDENYCA™, a biosimilar to Neulasta®, which was subsequently launched in January 2019.

We are also engaged in a separate lawsuit in which we have alleged that Coherus and others misappropriated our confidential information and trade secrets through hiring of former Amgen employees and that they have used such information to develop and market UDENYCA™. Trial is scheduled to begin on April 22, 2019.

Mylan Neulasta® Patent Litigation

On September 22, 2017, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the District Court for the Western District of Pennsylvania (the Pennsylvania Western District Court) against Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. (collectively, Mylan) for infringement of our ’707 Patent and the ’997 Patent. This lawsuit stems from Mylan’s submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen’s Neulasta® under the BPCIA. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Mylan from infringing the ’707 and ’997 Patents. On November 22, 2017, Mylan answered the complaint, denying patent infringement and alleging that the patents are invalid. On April 6, 2018, Mylan filed a motion for judgment on the pleadings of noninfringement of our ’707 Patent, which was denied by the court without prejudice on November 15, 2018. On June 4, 2018, the FDA approved Mylan’s Fulphila®, a biosimilar to Neulasta®, which was subsequently launched in July 2018. On November 20, 2018, the Pennsylvania Western District Court issued a claim construction opinion and order. On January 23 and 30, 2019, Mylan filed a renewed motion for judgment on the pleadings of noninfringement of the ’707 Patent and a motion for summary judgment of noninfringement of the ’997 Patent, respectively.

Pfizer NEUPOGEN® Patent Litigation

On July 18, 2018, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the Delaware District Court against Pfizer Inc. and Hospira Inc. (collectively, Pfizer). This lawsuit stems from Pfizer’s submission of an application for FDA licensure of a filgrastim product as biosimilar to Amgen’s NEUPOGEN®. Amgen has asserted infringement of the ’997 Patent and seeks, among other remedies, injunctive relief to prohibit Pfizer from infringing the ’997 Patent. On July 20, 2018, the FDA approved Pfizer’s NIVESTYM™, a biosimilar to NEUPOGEN®, which was subsequently launched in October 2018.

On August 9, 2018, Pfizer answered the complaint and counterclaimed seeking a declaration that Pfizer does not infringe Amgen's '997 Patent and that the patent is invalid. Trial is scheduled to commence on June 15, 2020.

Sandoz NEUPOGEN® Patent Litigation

On October 24, 2014, Amgen Inc. and AML (collectively, Amgen) filed a lawsuit in the U.S. District Court for the Northern District of California (the California Northern District Court) against Sandoz Inc., Sandoz International GmbH and Sandoz GmbH

(collectively, Sandoz) for infringement of our U.S. Patent No. 6,162,427 (the ’427 Patent) and various state law claims. The lawsuit stems from Sandoz filing an application for FDA licensure of a filgrastim product as biosimilar to NEUPOGEN® under the BPCIA, while having deliberately failed to comply with the BPCIA’s disclosure requirement to Amgen as the reference product sponsor. By its complaint, Amgen seeks, among other remedies, an injunction to cease Sandoz’s unauthorized reliance on Amgen’s Biologics License Application (BLA) for filgrastim and an injunction to prevent infringement of the ’427 Patent.

On March 19, 2015, the California Northern District Court issued an order dismissing with prejudice Amgen’s state law claims and entered judgment in favor of Sandoz Inc. on its cross-motion for partial judgment on the pleadings. The order also denied Amgen’s motion for a preliminary injunction, as well as Amgen’s motion for partial judgment on the pleadings. On a joint motion of the parties, on March 25, 2015, the California Northern District Court entered final judgment on the claims and counterclaims decided by the court’s March 19 order. The remaining patent infringement claim, counterclaim and defenses were stayed by the court pending appeal. On March 25, 2015, Amgen appealed both the judgment in favor of Sandoz Inc. and the denial of Amgen’s motion for preliminary injunction to the Federal Circuit Court. On May 5, 2015, the Federal Circuit Court entered an injunction prohibiting Sandoz Inc. from marketing, selling, offering for sale, or importing into the United States Sandoz’s FDA-approved Zarxio® biosimilar product until the Federal Circuit Court resolved the appeal.

On July 21, 2015, the Federal Circuit Court affirmed the California Northern District Court’s dismissal of Amgen’s state law claims concluding that the only remedies available for a biosimilar applicant’s failure to provide its BLA by the statutory deadline is to bring a patent infringement claim and seek those patent remedies provided by the statute. The Federal Circuit Court also concluded that a biosimilar applicant must give 180-day advance notice of first commercial marketing after the FDA has licensed the biosimilar product. Accordingly, the Federal Circuit Court entered an order that its previously entered injunction be extended through September 2, 2015 (180 days from Sandoz Inc.’s notice given after FDA approval).

In 2016, Sandoz filed a petition for certiorari with the U.S. Supreme Court and Amgen filed a conditional cross-petition for certiorari. Both petitions were granted and on June 12, 2017, the U.S. Supreme Court reversed the Federal Circuit Court ruling that a biosimilar applicant must wait to give the 180-day advance notice of first commercial marketing until after the FDA has licensed the biosimilar product, holding that such notice can be given either before or after the FDA approval. The U.S. Supreme Court also vacated the Federal Circuit Court’s decision that the only remedy available when a biosimilar applicant refuses to provide its BLA is to bring a patent infringement claim. The U.S. Supreme Court agreed with the Federal Circuit Court that there is no remedy under federal law for failing to make the disclosure but remanded the case to the Federal Circuit Court to determine whether California law would treat noncompliance with such requirement as unlawful and, if so, to determine whether the BPCIA pre-empts any additional remedy available under state law and whether Sandoz forfeited any pre-emption defense. On December 14, 2017, the Federal Circuit Court affirmed the California Northern District Court’s dismissal of Amgen’s state law claims, holding that the BPCIA pre-empts state law remedies for a biosimilar applicant’s failure to comply with the BPCIA’s disclosure requirement.

Following the California Northern District Court’s September 8, 2015 lift of the stay of the case, the parties continued to litigate the remaining patent infringement claim, counterclaim and defenses. On October 15, 2015, Amgen filed a first supplemental and amended complaint adding to the lawsuit Sandoz’s infringement of the ’878 Patent, which covers methods of purifying proteins. On September 13, 2017, by joint stipulation of the parties, the California Northern District Court dismissed from the case the parties’ respective claims and counterclaims related to the ’427 Patent. On October 25, 2017, Sandoz filed motions for summary judgment of noninfringement of the ’878 Patent and for summary judgment regarding damages. On December 19, 2017, the California Northern District Court granted Sandoz’s summary judgment of noninfringement. Sandoz’s motion for summary judgment regarding damages was denied as moot. On January 8, 2018, the California Northern District Court entered judgment of noninfringement of the ’878 and ’427 Patents and dismissed without prejudice Sandoz’s counterclaims of invalidity of the ’878 and ’427 Patents. On February 5, 2018, Amgen appealed the judgment to the Federal Circuit Court. A hearing on the appeal has been scheduled for March 4, 2019.

Sandoz Neulasta® Patent Litigation

On May 12, 2016, Amgen filed a lawsuit in the California Northern District Court against Sandoz and Lek Pharmaceuticals d.d. for infringement of the ’878 Patent and U.S. Patent No. 5,824,784 (the ’784 Patent) in accordance with the patent provisions of the BPCIA. The lawsuit stems from Sandoz filing an application for FDA licensure of a pegfilgrastim product as biosimilar to Neulasta®. On June 23, 2016, Sandoz responded to the complaint, denying infringement and seeking judgment that the patents-in-suit are invalid and/or not infringed. On December 7, 2016, by joint stipulation of the parties, the California Northern District Court dismissed from the case all claims and counterclaims related to the ’784 Patent. On October 25, 2017, Sandoz filed motions for summary judgment of noninfringement of the ’878 Patent and for summary judgment regarding damages. On December 19, 2017, the California Northern District Court granted Sandoz’s summary judgment of noninfringement of the ’878 Patent. Sandoz’s motion for summary judgment regarding damages was denied as moot. On January 8, 2018, the California Northern District Court entered judgment of noninfringement of the ’878 Patent and dismissed without prejudice Sandoz’s counterclaims of invalidity of the ’878 Patent. On February 5, 2018, Amgen appealed the judgment to the Federal Circuit Court. A hearing on the appeal has been scheduled for March 4, 2019.

PCSK9 Antibody Patent Litigation

U.S. Patent Litigation-Sanofi/Regeneron

On October 17, 2014, Amgen initiated a series of lawsuits in the Delaware District Court against Sanofi, Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc., and Regeneron Pharmaceuticals, Inc. (Regeneron) for patent infringement. On December 15, 2014, these lawsuits were consolidated by the Delaware District Court into a single case against Sanofi, Sanofi-Aventis U.S. LLC and Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc. (collectively, Sanofi) and Regeneron, addressing seven of our patents: U.S. Patent Nos. 8,563,698; 8,829,165 (the ’165 Patent); 8,859,741 (the ’741 Patent); 8,871,913; 8,871,914; 8,883,983; and 8,889,834. These patents describe and claim monoclonal antibodies to proprotein convertase subtilisin/kexin type 9 (PCSK9). By its complaints, Amgen seeks an injunction to prevent the infringing manufacture, use and sale of Sanofi and Regeneron’s alirocumab, a monoclonal antibody targeting PCSK9. On January 29, 2016, the Delaware District Court granted Amgen’s motion to amend the complaint to add AML and Amgen USA Inc. as plaintiffs and to add the allegation that defendants’ infringement of Amgen’s patents is willful.

On February 22, 2016, the Delaware District Court entered a stipulated order finding alirocumab and the drug product containing it, PRALUENT®, infringe certain of Amgen’s patents, including claims 2, 7, 9, 15, 19 and 29 of the ’165 Patent and claim 7 of the ’741 Patent. On March 18, 2016, the Delaware District Court entered judgment in favor of Amgen following a five-day jury trial and a unanimous jury verdict that these patent claims from the ’165 Patent and the ’741 Patent are all valid. On January 3, 2017, the Delaware District Court denied Sanofi and Regeneron’s post-trial motions seeking a new trial and for judgment as a matter of law, and on January 5, 2017, granted Amgen’s motion for a permanent injunction prohibiting the infringing manufacture, use, sale, offer for sale or import of alirocumab in the United States.

On January 12, 2017, Sanofi and Regeneron filed an appeal of the judgment and the permanent injunction to the Federal Circuit Court. On February 8, 2017, following a motion by Sanofi and Regeneron, the Federal Circuit Court entered a stay of the permanent injunction during the pendency of the appeal. On October 5, 2017, the Federal Circuit Court reversed in part the judgment of the Delaware District Court and remanded for a new trial two of Sanofi and Regeneron’s patent validity defenses (failure to meet the law’s requirements for patentability of written description and enablement of the claimed inventions), and affirmed the Delaware District Court’s judgment of infringement of claims 2, 7, 9, 15, 19 and 29 of the ’165 Patent and claim 7 of the ’741 Patent and patent validity on Sanofi and Regeneron’s third patent validity defense (finding that the claimed inventions were not obvious to a person of ordinary skill in the field of the patents). The Federal Circuit Court also vacated and remanded for further consideration by the Delaware District Court the permanent injunction. On July 23, 2018, Amgen filed a petition for certiorari with the U.S. Supreme Court seeking review of the Federal Circuit Court’s conclusion that the judgment affirming the validity of Amgen’s patents was based, in part, on an erroneous application of the law of written description. On January 7, 2019, the Supreme Court denied Amgen’s petition for certiorari.

On remand from the appellate court, the Delaware District Court scheduled a new trial to begin on February 19, 2019 on Sanofi and Regeneron’s challenges to the validity of our patents based on lack of written description and enablement of the claimed inventions. Consideration of damages and injunctive relief will follow, as appropriate. The court also entered judgment on the pleadings for Sanofi and Regeneron on Amgen’s claim of willful infringement.

Patent Disputes in the International Region

On February 24, 2016, the European Patent Office (EPO) granted European Patent No. 2,215,124 (EP 2,215,124) to Amgen. This patent describes and claims monoclonal antibodies to PCSK9 and methods of treatment. On February 24, 2016, Sanofi filed an opposition to the patent in the EPO seeking to invalidate it. In November 2016, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A. and Sanofi Winthrop Industrie S.A. filed a joint opposition against Amgen’s patent, and each of Eli Lilly and Company, Regeneron and Strawman Ltd. also filed oppositions to Amgen’s patent. Following a three-day hearing, on November 30, 2018, the EPO confirmed the validity of Amgen’s EP 2,215,124.

We are also involved in and expect future involvement in additional disputes regarding our PCSK9 patents in other jurisdictions and regions, including matters filed against us and that we have filed in the United Kingdom, Germany, France and Japan.

Hospira EPOGEN® (epoetin alfa) Patent Litigation

On September 18, 2015, Amgen filed a lawsuit in the Delaware District Court against Hospira, Inc. (Hospira), a subsidiary of Pfizer, for infringement of Amgen's U.S. Patent Nos. 5,856,298 (the '298 Patent) and 5,756,349 (the '349 Patent) in accordance with the patent provisions of the BPCIA and for a declaration that Hospira has failed to comply with certain requirements of the BPCIA. This lawsuit stems from the submission by Hospira under the BPCIA of an application for FDA licensure of an epoetin product as biosimilar to Amgen's EPOGEN®. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Hospira from using or selling infringing cells and/or product manufactured during the '298 or the '349 Patent terms and enjoining

Hospira from commencing commercial marketing of any biosimilar epoetin product until a date that is at least 180 days after Hospira provides legally effective notice to Amgen.

On August 19, 2016, Hospira responded to the complaint denying patent infringement and any violation of the BPCIA and seeking judgment that the patents-in-suit are invalid and not infringed by Hospira. On January 23, 2017, the Delaware District Court entered an order construing the claims of the ’349 and ’298 Patents and holding that two claims of the ’298 Patent are invalid for failure to properly narrow the claim on which they depend.

On September 22, 2017, after a five-day trial, the jury returned a verdict finding the ’298 Patent valid and infringed by Hospira and the ’349 Patent not infringed. The jury awarded Amgen $70 million in damages for Hospira’s infringement. On October 23, 2017, Hospira moved for judgment as a matter of law of noninfringement and invalidity of the ’298 Patent or, in the alternative, for reduction of the damage award or a new trial on the ’298 Patent.

On May 15, 2018, the FDA approved Hospira’s RETACRIT®, a biosimilar to EPOGEN®, which was subsequently launched on November 14, 2018.

On August 27, 2018, the Delaware District Court denied Hospira’s October 23, 2017, motion and entered final judgment on September 11, 2018. On October 3, 2018, Hospira filed a notice of appeal to the Federal Circuit Court and on October 15, 2018, Amgen filed a notice of cross-appeal.

Litigation relating to our Biosimilar Products

MVASI™ (bevacizumab-awwb) Patent Litigation

On October 6 and October 18, 2017, Genentech, Inc. (Genentech) and City of Hope filed separate lawsuits in the Delaware District Court respectively alleging Amgen’s infringement of (i) 24 of the 27 patents listed by Genentech in the BPCIA exchange and (ii) 25 of the same 27 patents, in each case by Amgen’s submission for FDA licensure of MVASI™ as biosimilar to Genentech’s Avastin® (bevacizumab), and for non-compliance with certain provisions of the BPCIA. On December 6, 2017, Genentech and City of Hope amended their complaints to allege that Amgen will also infringe newly issued U.S. Patent No. 9,795,672. On April 17, 2018, the Delaware District Court granted Amgen’s motion to dismiss certain claims by Genentech and City of Hope that Amgen had not complied with the BPCIA. Amgen responded to the complaints on May 1 and June 5, 2018, respectively, denying patent infringement and any violation of the BPCIA and seeking judgment that the patents-in-suit are invalid, unenforceable and/or not infringed by Amgen. On May 22 and June 19, 2018, respectively, Genentech and City of Hope moved to dismiss from each case all of Amgen’s counterclaims and certain of Amgen’s defenses.

On August 31, 2018, in accordance with the scheduling order issued by the Delaware District Court, Genentech and City of Hope reduced the number of asserted patents in each lawsuit to 8, asserting the same patents in each case. On October 22, 2018, the two cases were consolidated by the court. Trial is scheduled to begin on July 13, 2020.

KANJINTI™ (trastuzumab) Patent Litigation

On June 21, 2018, Genentech and City of Hope filed a lawsuit in the Delaware District Court alleging Amgen’s infringement of 37 patents by Amgen’s submission of an application for FDA licensure of KANJINTI™, Amgen’s biosimilar version of Genentech’s Herceptin® (trastuzumab). On July 19, 2018, Genentech, City of Hope and Amgen filed a joint stipulation to dismiss certain of the patents from the lawsuit and Genentech and City of Hope filed an amended complaint narrowing its allegations of infringement to 18 of the 37 patents. Among other remedies, Genentech and City of Hope seek injunctive relief prohibiting patent infringement.

On August 23, 2018, Genentech and City of Hope moved to dismiss Amgen’s unenforceability counterclaims and affirmative defense. On November 7, 2018, in accordance with the scheduling order issued by the Delaware District Court, Genentech and City of Hope reduced the number of asserted patents from 18 to 10. On January 17, 2019, Genentech and the City of Hope filed a second amended complaint that removed one of the remaining 10 asserted patents and added a different patent. Trial is scheduled to begin on or after December 9, 2019.

AMJEVITA™ (adalimumab-atto) / AMGEVITA™ Patent Litigation

On January 24, 2019, Coherus filed a lawsuit in the Delaware District Court that the formulation of AMJEVITA™ infringes three patents: U.S. Patent Nos. 10,155,039; 10,159,732; and 10,159,733. By its complaint, Coherus seeks, among other remedies, injunctive relief prohibiting patent infringement.

Amgen has also been sued in a number of European countries by Fresenius Kabi Deutschland GmbH (Fresenius), alleging that AMGEVITA™ infringes various patents of Fresenius and seeking, among other remedies, injunctive relief prohibiting patent infringement.

U.S. Attorney's Office for the District of Massachusetts-Patient Assistance Investigation

Amgen, together with other companies in our industry, has received inquiries from the U.S. Attorney's Office for the District of Massachusetts relating to support of charitable 501(c)(3) organizations that provide financial assistance to Medicare patients. Amgen is cooperating with this ongoing inquiry.

Commitments

Lease commitments

We lease certain facilities and equipment related primarily to administrative, R&D, sales and marketing activities under noncancelable operating leases that expire through 2029. The following table summarizes the minimum future rental commitments under noncancelable operating leases as of December 31, 2018 (in millions):

| | Amounts |
|---|---|
| 2019 | $ 164 |
| 2020 | 126 |
| 2021 | 113 |
| 2022 | 64 |
| 2023 | 56 |
| Thereafter | 46 |
| Total minimum operating lease commitments | $ 569 |

Included in the table above are future rental commitments for abandoned leases in the amount of $222 million. There were no material charges for lease abandonments related to the restructuring plan that commenced in 2014. See Note 2, Restructuring. We expect to receive total future rental income of $203 million relating to noncancelable subleases of abandoned facilities. Rental expenses on operating leases for the years ended December 31, 2018, 2017 and 2016, were $166 million, $159 million and $134 million, respectively.

U.S. repatriation tax commitments

Under the 2017 Tax Act, we elected to pay the repatriation tax related primarily to our prior indefinitely invested earnings of our foreign operations in eight annual installments. See Note 7, Income taxes. The following table summarizes the remaining scheduled repatriation tax payments as of December 31, 2018 (in millions):

| | Amounts |
|---|---|
| 2019 | $ 586 |
| 2020 | 586 |
| 2021 | 586 |
| 2022 | 586 |
| 2023 | 1,099 |
| Thereafter | 3,296 |
| Total remaining U.S. repatriation tax commitments | $ 6,739 |

21. Major customers

In the United States, we sell primarily to pharmaceutical wholesale distributors that we utilize as the principal means of distributing our products to healthcare providers. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

We had product sales to three customers, each of them accounting for more than 10% of total revenues for each of the years ended December 31, 2018, 2017 and 2016. For the year ended December 31, 2018, on a combined basis, these customers accounted for 84% and 98% of total gross revenues and U.S. gross product sales, respectively, as shown in the following table. Certain information with respect to these customers was as follows (dollar amounts in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| AmerisourceBergen Corporation: | | | |
| Gross product sales | $12,091 | $10,742 | $10,100 |
| % of total gross revenues | 33 % | 31 % | 31 % |
| % of U.S. gross product sales | 39 % | 37 % | 38 % |
| McKesson Corporation: | | | |
| Gross product sales | $11,434 | $10,625 | $9,710 |
| % of total gross revenues | 31 % | 30 % | 30 % |
| % of U.S. gross product sales | 35 % | 35 % | 34 % |
| Cardinal Health, Inc.: | | | |
| Gross product sales | $7,475 | $7,049 | $6,520 |
| % of total gross revenues | 20 % | 20 % | 20 % |
| % of U.S. gross product sales | 24 % | 24 % | 24 % |

As of December 31, 2018 and 2017, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 76% and 75%, respectively, of net trade receivables on a combined basis. As of December 31, 2018 and 2017, 23% and 25%, respectively, of trade receivables, net, were due from customers located outside the United States—primarily in Europe. Our total allowance for doubtful accounts as of December 31, 2018 and 2017 was not material.

22. Quarterly financial data (unaudited)

The following tables summarize the Company's unaudited financial data on a quarterly basis. The sum of the quarterly earnings (loss) per-share amounts may not equal the amount reported for the full year because per-share amounts are computed independently for each quarter and for the full year based on respective weighted-average shares outstanding and dilutive securities.

Quarterly financial data is summarized as follows (in millions, except per-share data):

| | 2018 Quarters ended | | | |
|---|---|---|---|---|
| | December 31 | September 30 | June 30 | March 31 |
| Product sales | $6,001 | $ 5,510 | $5,679 | $ 5,343 |
| Gross profit from product sales | $4,905 | $ 4,473 | $4,655 | $ 4,399 |
| Net income | $1,928 | $ 1,859 | $2,296 | $ 2,311 |
| Earnings per share: | | | | |
| Basic | $3.04 | $ 2.88 | $3.50 | $ 3.27 |
| Diluted | $3.01 | $ 2.86 | $3.48 | $ 3.25 |
| | 2017 Quarters ended | | | |
| | December 31 | September 30 | June 30 | March 31 |
| Product sales | $5,569 | $ 5,453 | $5,574 | $ 5,199 |
| Gross profit from product sales | $4,510 | $ 4,463 | $4,550 | $ 4,203 |
| Net (loss) income | $(4,264) | $ 2,021 | $2,151 | $ 2,071 |
| (Loss) earnings per share: | | | | |
| Basic | $(5.89) | $ 2.78 | $2.93 | $ 2.81 |
| Diluted[1] | $(5.89) | $ 2.76 | $2.91 | $ 2.79 |

(1) During periods of net loss, diluted loss per share is equal to basic loss per share because the antidilutive effect of potential common shares is disregarded.

SCHEDULE II
AMGEN INC.
VALUATION AND QUALIFYING ACCOUNTS
Years ended December 31, 2018, 2017 and 2016
(In millions)

| Allowance for doubtful accounts | Balance at beginning of period | Additions charged to costs and expenses | Other additions | Deductions | Balance at end of period |
|---|---|---|---|---|---|
| Year ended December 31, 2018 | $ 51 | $ 1 | $ — | $ 4 | $ 48 |
| Year ended December 31, 2017 | $ 51 | $ 4 | $ — | $ 4 | $ 51 |
| Year ended December 31, 2016 | $ 55 | $ 11 | $ — | $ 15 | $ 51 |

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